Taking Charge After Stroke

A novel, community-based intervention
to improve the lives of people with stroke

By Vivian Wai Yin Fu

A thesis submitted to the Victoria University of Wellington
in fulfilment of the requirements for the degree of
Doctor of Philosophy

Victoria University of Wellington, 2019

Abstract

Background and aims

Stroke is the third leading cause of disability worldwide. Despite the recent development of hyper-acute therapies for stroke, outcomes for people with stroke and types of rehabilitation interventions have remained unchanged. Rehabilitation in New Zealand is largely therapy-based and uses goal setting as a main component, but evidence for effectiveness of these methods is weak. Attempts to enhance the effects of rehabilitation using a stroke liaison officer or a caregiver to lead rehabilitation at home have had no effect on outcomes. However, self-management interventions have shown some promise.

The Take Charge session is a novel, community-based, self-management intervention, which was shown to significantly improve both independence and health-related quality of life at 12 months following stroke in Māori and Pacific New Zealanders. We formalised the components of the Take Charge session, based upon Self Determination Theory and qualitative research about the importance of Taking Charge in recovery. This allowed us to retest the intervention in a different population of people with stroke.

We hypothesised that: (1) the beneficial effect of the Take Charge session would be reproducible in a larger cohort of non-Māori, non-Pacific people with stroke, and (2) that two Take Charge sessions would have a greater positive effect on health-related quality of life than one alone.

Methods

We randomised 400 people within 16 weeks of acute stroke who had been discharged to community living at seven centres in New Zealand to either a single Take Charge

session (TCS 1, n = 132), two Take Charge sessions (TCS 2, n = 138), or a control intervention (n = 130). The primary outcome was the Physical Component Summary score (PCS) of the Short Form 36 (SF-36) at 12 months following index stroke, comparing any Take Charge session exposure to control. Secondary outcomes included the PCS of the Short Form 12 (SF-12) at six months, participation measured by the Frenchay Activities Index at six and 12 months, and activities measured by the Barthel Index at six and 12 months. Outcome measures were performed by an assessor masked to allocation.

Results

At 12 months following stroke, participants in either of the Take Charge groups (TCS 1 + TCS 2) scored 2.9 (95% CI 0.95 to 4.9, $p = 0.004$) points higher (better) than control on the SF-36 PCS. This difference was statistically and clinically significant. The effect size remained significant when we adjusted for pre-specified baseline variables, including age, gender, and baseline stroke severity. Furthermore, SF-12 PCS at six months showed improvement in similar direction and effect size, and improvement in participation was statistically significant at 12 months. There was a positive dose effect with each exposure to the Take Charge session predicting a 1.9 (95% CI 0.8 to 3.1, $p < 0.001$) point increase in the 12-month SF-36 PCS.   Subsequently, we conducted an individual patient meta-analysis of the Take Charge session, pooling data with the initial Māori and Pacific Stroke Study. The pooled effect of any exposure to the Take Charge session was 3.74 (95% CI 1.96 to 5.51) points greater than control.

Conclusion

The Take Charge session – a simple, self-management intervention, improved health-related quality of life and participation at 12 months. This thesis provides evidence for implementing such an intervention into routine, post-stroke care, to improve the quality of life of people with stroke in the long term.

Acknowledgements

Table of Contents

List of Tables

List of Figures

Style Issues

References are cited in the format of the American Psychological Association (APA) format.

It is acknowledged that APA style requires the use of words for approximations of numbers of days, months, and years. It is also standard practice to use words for numbers from one to nine. This thesis frequently uses the number six in particular, because the study's follow-up is timed at six months and 12 months.

However, for the sake of readability and brevity, in some parts of this thesis the preceding number will be written as a numeral. For example, 3 months may be used instead of three months. Where the length of time is used as an adjective or descriptor, this will be signified with a hyphen, for example: 6-month questionnaire. Numbers used as descriptors will also be written in numerals, for example: Day 5-7 Barthel Index.

In other contexts, the APA style rules about the formatting of numbers will apply.

List of Abbreviations

AAP	Adelaide Activities Profile
ADL	Activities of daily living
AMP-C	Autonomy, Mastery, Purpose, Connectedness measure
ANOVA	Analysis of variance
ANCOVA	Analysis of covariance
ARCOS	Auckland Regional Community Stroke Study
ATTEND	Family-led Rehabilitation after Stroke in India trial
BI	Barthel Index
CI	Confidence interval
CSS	Copenhagen Stroke Study
CT	Computed tomography (scan)
DALY	Disability-adjusted life year
DHB	District Health Board
DVD	Digital video disc
EADL	Extended activities of daily living
ECR	Endovascular clot retrieval (thrombectomy)
EQ-VAS	EuroQol Visual Analogue Scale
EuroQol	European Quality of Life group
EQ-5D-5L	EuroQol – 5 Dimensions – 5 Levels instrument
FAI	Frenchay Activities Index
FIM	Functional Independence Measure
GP	General practitioner
HDEC	Health and Disability Ethics Committee of New Zealand
HRC	Health Research Council of New Zealand
ICF	International Classification of Functioning

ICIDH	International Classification of Impairments, Disabilities and Handicaps – two versions referred to as ICIDH-1 (1980) and ICIDH (1999) – superseded by WHO-ICF since 2001
ICH-GCP	International Conference of Harmonisation – Good Clinical Practice
IQR	Interquartile range
IST	International Stroke Trial
IV	Intravenous
LACI	Lacunar infarction
LOS	Length of stay
MaPSS	Māori and Pacific Stroke Study
MCID	Minimal clinically important difference
MCS	Mental Component Summary score
MRINZ	Medical Research Institute of New Zealand
mRS	Modified Rankin Scale
NEADL	Nottingham Extended Activities of Daily Living scale
NNH	Number needed to harm
NNT	Number needed to treat
NS	Not significant
NZ	New Zealand
OCSP	Oxfordshire Community Stroke Project classification system (see PACI, POCI, LACI, TACI, and PICH)
PACI	Partial anterior circulation infarction
PAM	Patient Activation Measure
PCS	Physical Component Summary score
PHQ-2	Patient Health Questionnaire-2
PICH	Primary intracerebral haemorrhage
POCI	Posterior circulation infarction

QALY	Quality-Adjusted Life Year
RA / RC	Research assistant / research clinician
SD	Standard deviation
SDT	Self-Determination Theory
SF-36v2	Version 2 of the Short Form 36-item questionnaire
SRM	Standardised response mean
SUTC	Stroke Unit Trialists' Collaboration
TaCAS	Taking Charge After Stroke (study)
TACI	Total anterior circulation infarction
TCS	Take Charge session intervention
tPA	Thromboplasminogen activator (= thrombolysis)
V1	Randomisation visit (first visit by research clinician)
V2	Second visit by research clinician, received by 1/3 of participants who were allocated to two Take Charge sessions
WHO	World Health Organisation

Glossary

Aotearoa	Māori name for New Zealand. Literal meaning translates to "land of the long white cloud".
Pākehā	Māori language term for New Zealanders of European descent, or "New Zealand European".
Pasifika	Indigenous peoples of the Pacific islands.
Whānau	Māori language term for "family" or "extended family".

1 Introduction

The purpose of this chapter is to describe the current burden of stroke and the expected outcomes after stroke bearing in mind the advent of recently introduced therapies. This will provide the context in which a novel intervention, the Take Charge session, is designed to improve outcomes such as quality of life and dependency after stroke.

Stroke is a significant public health problem in New Zealand and worldwide. With little to no warning, stroke can affect a person's cognitive, speech, sensory or motor functions resulting in residual impairments that range from mild to catastrophic. In New Zealand, stroke affects approximately 9000 people per year and is the third leading cause of death ("Facts and fallacies | Stroke Foundation of New Zealand," n.d.). Globally, in 2013, there were 25.7 million stroke survivors, 6.5 million deaths from stroke, 10.3 million new stroke events, and 113 million Disability Adjusted Life Years (DALYs) due to stroke (Feigin, Krishnamurthi, Parmar, et al., 2015).

Previously considered as a disease of the elderly, it is especially concerning that the rates of stroke affecting younger people are rising. The 4th Auckland Regional Community Stroke Study (ARCOS IV) found that 54% of all first strokes and 51% of all recurrent strokes occurred in people younger than 75 (Feigin, Krishnamurthi, Barker-Collo, et al., 2015). Worldwide, two-thirds of all stroke occur in people under the age of 70 years (Feigin et al., 2016). The younger the age of stroke onset, the longer a person with stroke has to live with residual disability, i.e., the higher the number of disability-adjusted life-years (DALYs) they incur.

One would hope that advances in medical knowledge and therapies would mitigate these concerning statistics. Unfortunately, little has changed for the majority of people with

stroke. In New Zealand, outcomes for people living in the community with stroke have remained relatively constant for the past 20 years (McNaughton, Weatherall, McPherson, Taylor, & Harwood, 2002). 80% of all persons with stroke survive their hospital admission to discharge. One-fifth of these survivors are discharged to institutional care due to significant impairment. Of the remainder who are discharged into the community, one-third are dependent on others for basic activities of daily living (ADLs). The other two-thirds are independent but not necessarily fully recovered from their stroke. These figures, determined in a Wellington cohort in 1997, are comparable to the outcomes of 1127 people with stroke in Auckland in 2002-2003. By nine months after stroke, 30% of these people were dead, 20% were institutionalised, and 40% were dependent on others for ADLs (McNaughton et al., 2011).

Unfortunately, the problem of stroke is growing. Absolute numbers of people who have a stroke, stroke survivors, stroke-related deaths, and the overall global burden of stroke are all increasing (Krishnamurthi et al., 2013). In addition, 80% of all people with stroke live in resource-poor countries, where access to specialist stroke care and rehabilitation is either limited or unavailable. Stroke in low-income and middle-income countries contributes to 88% of the global stroke disability burden (Feigin et al., 2016). This over-representation may be a result of increasing rates of hypertension, diabetes, tobacco use, and salt and sugar consumption, particularly in countries lacking adequate public health prevention measures and access to novel treatment. At the other end of the spectrum, people with stroke living in high-income countries have benefited from improved stroke care, resulting in longer life expectancy and population growth. Consequently, the absolute numbers of stroke survivors globally are expected to increase. In the United States, the number of people aged over 45 is predicted to double in the next 40 years, meaning the total number of stroke events will be 2.25 times the current rate (Howard & Goff, 2012).

It is irrefutable that stroke is a growing health problem, and that the number of people affected by stroke will increase. In Aotearoa New Zealand, the lifetime cost of first-ever stroke, estimated from Australian cost data, is $400 million (Cadilhac, Carter, Thrift, & Dewey, 2009). A high proportion of this cost is due to residual disability and dependence of people with stroke. It is, therefore, essential to grasp what is being done for people with stroke in the current climate to understand gaps that need to be addressed. To make sense of the effectiveness of current treatments, we need to measure outcomes that are relevant to health systems, to society, and to individuals.

The World Health Organisation International Classification of Function, Disability and Health (ICF) is a framework which incorporates the fundamental ways an illness or disease affects a person. Therefore, in addition to death, discharge destination, and dependence, outcomes at the levels of quality of life, participation restriction, and activity limitation hold importance. The literature review will explore the evidence for interventions which target improvement at these levels. The following section will outline the current treatments for people with stroke.

1.1   Structure of the thesis

In Chapter 2 I will review the literature covering:

- Current research: hyper-acute and acute treatment for stroke
- Treatment for stroke in the community setting
    - Therapy-led rehabilitation
    - Goal setting
    - Stroke liaison worker
    - Caregiver-led rehabilitation
- Self-management interventions
- The Māori and Pacific Stroke Study (MaPSS) and the consequences of its results

In Chapter 3, I present the **hypotheses** of the Taking Charge After Stroke study (TaCAS). A comprehensive description of the **methodology** and instruments used in TaCAS follows. The statistical plan and a description of my role in the study concludes this chapter.

In Chapter 4, the **results** of the TaCAS study will be discussed, including baseline characteristics, primary and secondary outcomes, and pre-specified subgroup analyses. Other relevant analyses of interest will be presented.

In Chapter 5, I will **discuss** the main findings of the TaCAS study, its strengths and weaknesses, and the implications of our conclusions for clinical practice. This chapter will also speculate on how Take Charge might work, and recommend directions for future research.

In Chapter 6, this thesis **concludes** with a summary of the study and its findings. Chapter 7 contains the **references**, and the **appendix** material is located in Chapter 8.

2 Literature Review

2.1   Current treatments for stroke

There are treatments used to treat stroke today which have been shown to improve individual patient outcomes. These outcomes include reduction in mortality and disability. This section will review these interventions and present the evidence supporting their use. These interventions include: organised care within a stroke unit, antiplatelet therapy after ischaemic stroke, intravenous thrombolysis (IV tPA), and endovascular clot retrieval (ECR), also known as mechanical thrombectomy.

2.1.1   Acute treatments for stroke

In the early 1990s, evidence emerged that providing organised stroke care within a designated stroke unit significantly improved the outcomes of people with stroke (Kalra, 1994). For all intents and purposes, a stroke unit would look physically identical to a general medical ward, but the organised stroke care provided within it incorporated the needs of the people with stroke.

When tested in a randomised controlled trial against care in a general ward, people with stroke cared for in the stroke unit achieved a higher Barthel Index (BI) score at discharge (15 vs. 12) (Kalra, 1994). Those in the stroke unit also improved their median BI score within the first two weeks, reaching a plateau by six weeks, while those who received general care took longer, reaching their plateau by 12 weeks. Both groups received the same amount of rehabilitation therapy. From this study, the effectiveness of the stroke unit on functional recovery and shorter length of stay was thought to be due to better organisational factors, and closer liaison between the person, their family, and the treating team.

Later, organised stroke unit care was further characterised as having coordinated multidisciplinary rehabilitation, education programmes and training in stroke, and specialisation of medical and nursing staff. A systematic review confirmed that compared with people with stroke treated in a general medical ward, those who received treatment in an inpatient stroke unit achieved more rapid and higher level of functional recovery. They were also less likely to be dead or dependent at one year after stroke (Stroke Unit Trialists' Collaboration, 1997).

By 2003, the New Zealand Guideline for Management of Stroke recognised that the use of stroke units was a critical area in which changing practice would make an important difference to outcomes. The guideline recommended that all District Health Boards (DHBs) 'should provide organised stroke services' and 'people…should expect to be managed in a stroke unit by a team of health professionals with expertise in stroke and rehabilitation' (Baskett & McNaughton, 2003).

However, organised stroke inpatient care is not accessible in all New Zealand centres. When adherence to this guideline was last audited in 2013, only seven large DHBs – responsible for the care of approximately 62% of the New Zealand population - had a dedicated stroke rehabilitation unit or a designated area for stroke (McNaughton, McRae, Green, Abernethy, & Gommans, 2014). Similarly, the most recent Auckland Regional Community Stroke Study (ARCOS) showed that while hospitalisation for acute stroke had increased, only 51% of people who were admitted were cared for within an acute stroke unit (Feigin, Krishnamurthi, Barker-Collo, et al., 2015).

The latest Cochrane systematic review of organised stroke care reported a number needed to treat (NNT) of 33 to prevent one death, and an NNT of 17 to prevent one person dying or becoming disabled (Stroke Unit Trialists' Collaboration, 2013). Furthermore, a separate analysis of the ARCOS study participants found no significant

differences in cost between people with stroke admitted to a stroke unit and a general ward (Te Ao, Brown, Feigin, & Anderson, 2012). The incremental cost-utility ratio fell substantially from NZ$42 813 per QALY to NZ$6747 per QALY when lifetime costs and outcomes were taken into account. Therefore, all hospitals should ideally have an inpatient stroke unit, a simple, cost-effective measure which saves lives.

Another relatively cheap intervention is antiplatelet therapy for acute ischaemic stroke. Antiplatelets limit ongoing clot formation and extension of an existing clot, thereby limiting the size of the stroke and reducing the extent of neuronal damage. Antiplatelets were hypothesised to be effective in ischaemic stroke due to their effectiveness in secondary prevention of other ischaemic conditions, such as myocardial infarction. This hypothesis was confirmed in two large randomised controlled trials of aspirin against placebo, the Chinese Acute Stroke Trial and the International Stroke Trial (Chen, 1997; International Stroke Trial Collaborative Group, 1997).

Data from these studies comprised over 40,000 people with stroke and contributed to 98% of the Cochrane systematic review of this therapy. The review authors concluded that aspirin 160mg – 300mg, given within 48 hours of onset of presumed ischaemic stroke, reduced the risk of early recurrent ischaemic stroke (Sandercock et al., 2014). The odds ratio (OR) for death or dependence in people with stroke taking aspirin was 0.95 (95% CI 0.91 – 0.99, p =0.008). This equated to an NNT of 79 to prevent one person from being dead or dependent after a stroke. The OR for recurrent stroke in the first 30 days was 0.77 in favour of aspirin (95% CI 0.68 – 0.86, p < 0.00001).

Aspirin is now part of routine treatment, commenced within 48 hours of acute ischaemic stroke, including in the setting of embolic stroke of unknown source (Stroke Foundation of New Zealand and New Zealand Guidelines Group, 2010). When other, higher risk, causes of a prothrombotic state – such as atrial fibrillation – are not identified, aspirin

use is often maintained lifelong for secondary prevention of stroke. It is a common, inexpensive medication, with a relatively safe, well-recognised risk profile.

2.1.2   Hyper-acute treatments for stroke

In recent times, perhaps in the past 30 years or so, research has focused on developing novel treatments targeting the hyper-acute phase of stroke. This is because during the first few hours after symptom onset, the ultimate goal of treatment is to reperfuse brain tissue, to curb the amount of brain damage occurring. The lack of additional, effective treatments for a person with stroke who presented promptly after onset of ischaemic stroke symptoms was the main driver for research interest in this area.

Consequently, two successful treatments were developed. The first was thrombolysis using intravenous tissue plasminogen activator (tPA), using agents such as alteplase or tenecteplase which are powerful at dissolving clots. The second was relatively recent technology known as thrombectomy or endovascular clot retrieval (ECR), where a clinician feeds a catheter through blood vessels into the large vessels within the brain, then deploys a mechanical device to remove an established clot.

These therapies have risks. There are a number of safety concerns about tPA. First, tPA must be administered within the first 3.5 – 4 hours of onset of stroke symptoms. The risk of harm to the person with stroke from bleeding increases the later tPA is given. At approximately 5 hours after stroke onset, the risk of harm starts to outweigh the risk of benefit as the OR of a good outcome (modified Rankin Scale [mRS] score of 0 – 1) approaches 1 (Emberson et al., 2014). The risk of haemorrhagic transformation from tPA increases as the ischaemic core becomes more established over time. As a result, within the first seven to 10 days of stroke, mortality is higher in people with stroke who receive tPA compared to those who do not (Wardlaw, Murray, Berge, & del Zoppo, 2014).

In a Cochrane systematic review, investigators pooled data from 27 tPA trials, albeit all with a degree of heterogeneity. Mortality data were available for all 27 trials included within the Cochrane review. There was a modest but significant increase in deaths from all causes within scheduled follow-up, from 18.0% in controls to 19.4% in participants allocated to thrombolysis (OR 1.18, CI 1.06 to 1.30, $p < 0.002$). In absolute terms, this represented an extra 15 (95% CI six fewer to 30 more) deaths at the end of follow-up, per 1000 participants treated with thrombolysis. There was a significant four-fold increase in symptomatic intracranial haemorrhage with thrombolysis in 7.5% of those allocated to tPA compared to 1.7% of those allocated to control (OR 3.75, 95% CI 3.11 to 4.51, $p < 0.00001$) with no statistically significant between-trial heterogeneity ($p = 0.36$). This represents an extra 60 (95% CI 50 to 65) symptomatic intracranial haemorrhages per 1000 participants treated with tPA (Wardlaw et al., 2014).

The pooled evidence for IV tPA showing benefit in reducing dependency is difficult to interpret due to clinical heterogeneity and the involvement of the pharmaceutical industry in funding these trials, especially the larger trials. After analysis of pooled estimated effects the conclusion was that when tPA was given within 3.5 hours, it had an NNT of 17 to prevent one unfavourable outcome (mRS 2 or higher) (Wardlaw et al., 2014). In New Zealand, attempts have been made to streamline inefficient internal conditions to optimise the proportion of people who are eligible for treatment within the safe window, largely through increasing awareness that 'Time is Brain'. Door-to-needle time is used as a measure of efficiency of services involved in inpatient thrombolysis. Thrombolysis is available in most New Zealand hospitals for the treatment of acute ischaemic stroke.

Over time it was noted that tPA was less effective at re-canalising proximal large artery occlusions. This reduced efficacy was thought to be due to a larger clot burden (Bhatia et al., 2010). In response, the mechanical device industry developed and tested devices to

extract the clot – a technique known as endovascular clot retrieval (ECR). The results of early randomised controlled trials (RCTs) were disappointing, showing that ECR caused greater harm and significantly poorer outcomes than medical treatment alone (Broderick et al., 2013; Ciccone et al., 2013; Kidwell et al., 2013).

However, industry persisted with the development of retrieval devices. In 2015, five RCTs reported ECR as being superior to standard medical therapy for ischaemic stroke (Berkhemer et al., 2015; Campbell et al., 2015; Goyal et al., 2015; Jovin et al., 2015; Saver et al., 2015). Overall, thrombectomy trials have shown an NNT of 6-7 to achieve functional independence in one patient (Rodrigues et al., 2016).

Thrombectomy is an invasive procedure performed by an experienced neuro-interventionalist who deploys the device under fluoroscopic guidance. It requires access to an interventional suite with radiological equipment, and the support of a team of specialist technicians and nurses. In Aotearoa New Zealand, neurologists are not trained in intervention, and a neuro-interventional fellowship has only been offered to Australasian neurology trainees since 2017. The majority of ECRs are undertaken by interventional radiologists, relying on a mutual relationship and service plan agreed between radiology and neurology departments.

A definite bonus of the introduction of IV tPA and ECR to Aotearoa New Zealand has been increased public awareness of stroke. Public health campaigns and messages conveyed in the mainstream media have emphasised the importance of presenting to hospital as soon as possible after symptom onset to increase the likelihood for being eligible for these treatments. Unfortunately, the absolute numbers of people who will benefit from IV tPA and thrombectomy are far fewer than the total number of people with stroke each year (see Table 1).

There are significant limitations to the uses of IV tPA and ECR. As previously mentioned, time is a key factor. IV tPA is unable to be given after 4.5 hours following onset of symptoms, or if the time of symptom onset is unknown, for example, in a wake-up stroke, or if the patient is unable to describe or recall the onset due to impairment of communication or cognition (Stroke Foundation, 2017).

Trials testing the safety of timing for ECR are continuing. During the research phase of this thesis, two international trials were published showing thrombectomy to be safe and beneficial when performed in selected people with stroke up to 24 hours after onset (Albers et al., 2017; Nogueira et al., 2018). Specialised imaging techniques were required for selecting eligible people with stroke.

Timely access to radiological investigations such as computed tomography (CT), CT angiography (CTA), and CT perfusion (CTP) is vital for establishing the diagnosis and whether thrombectomy is indicated. Thrombectomy has no place in the management of strokes caused by small vessel disease (lacunar stroke), or stroke of unknown aetiology (where one cannot visualise a clot on imaging), or embolic stroke with a sizeable ischaemic core. The imaging investigations mentioned above determine whether ECR will be beneficial; however these (especially CTP) are not widely available.

As with aspirin, these two new treatments are only useful for people with stroke with ischaemic stroke. Since approximately 15% of strokes in New Zealand are due to intracerebral haemorrhage, 85% of strokes are deemed to be ischaemic by default. Together, the classifications of lacunar stroke and stroke of unknown aetiology comprise half of ischaemic strokes which translates to thrombectomy being ineffective in at least 40% of all people with stroke (Krishnamurthi et al., 2017). Contraindications to IV tPA and ECR include intracerebral haemorrhage; subarachnoid haemorrhage; surgery, head

injury, or stroke within the last three months of the current stroke; and coagulopathy (Stroke Foundation, 2017).

Other barriers to accessing endovascular therapy include New Zealand's geography, problems with flow in the emergency department, and the lack of coordinated triage and transport to tertiary centres from rural or secondary hospitals. In New Zealand, ECR is only available in main centres, such as Auckland and Christchurch, with variable availability in Wellington at the time of writing. The service is heavily dependent upon the budget of the DHB and buy-in from interventional neuroradiology colleagues. These barriers contribute further to the low absolute numbers of people with strokes who receive thrombectomy each year. Table 1 illustrates a 'best case' scenario of absolute numbers receiving the various treatments in New Zealand every year.

In high volume, tertiary centres which have well developed acute stroke pathways and clinicians who are experienced in administering tPA, only approximately 5% of people with ischaemic stroke end up being treated with IV tPA (Feigin, Krishnamurthi, Barker-Collo, et al., 2015). Ultimately, in the setting of multicentre, international RCTs where investigators who work at participating hospitals are motivated and equipped to recruit maximal numbers of people with stroke, eligibility is approximately 5 – 15% for IV tPA and 3% for thrombectomy (Jovin et al., 2015).

New Zealand's highest volume hospital offering ECR is Auckland City Hospital, New Zealand's sole quaternary hospital. In a review of 33 people with stroke treated with thrombectomy at Auckland City Hospital, Barber and colleagues envisaged treating 50 people with stroke a year using a hyper-acute stroke treatment pathway to receive people with stroke from the Northern Region (Barber et al., 2015). If successful, this figure would equate to treating 0.5% of all strokes suffered in New Zealand with ECR. In other words, even if the other two major centres – Christchurch and Wellington – were able to

match these rates, 99% of people with stroke in New Zealand would still not be treated with ECR.

Furthermore, endovascular treatments come at considerable financial cost. In one cost-utility analysis, the incremental cost-effectiveness of IV tPA given with 3.5 to 4 hours, compared to treatment without tPA, was $22,000 per QALY gained (Tung, Win, & Lansberg, 2011).   A UK cost-effectiveness study of ECR showed an incremental cost per QALY gained over a 20 year period to be $11,651 (Ganesalingam et al., 2015). A more recent study that modelled ECR in an American setting found an incremental cost-effectiveness ratio for endovascular treatment (compared with standard care) of $3110 per QALY, although cost-effectiveness was lower in more distal occlusions and with established ischaemic injury seen on CT (Kunz et al., 2016).

Table 1 compares the hypothetical effects of the treatments outlined thus far, and estimates of the number of people who will benefit, and the number who will be harmed in New Zealand, based on reported NNTs.

Table 1. Estimated effect of interventions on outcome of reducing dependence in all NZ stroke people with stroke per year (approx. 9000)

	Interventions that reduce dependence after stroke			
	Organised stroke care	Acute aspirin	IV thrombolysis	Mechanical thrombectomy
No. of people with stroke eligible per year	9000	7650[b]	450 – 1350[c]	270[f]
Best case scenario no. of people with stroke eligible	5580[a]	7650	382[d]	50[g]
Number needed to treat to benefit 1 person (NNT)	18	79	17[e]	5.3[h]
Number needed to treat to cause harm (symptomatic intracranial bleeding) in 1 person (NNH)	0	574	17[e]	33[h]
Best case no. of people who will benefit from treatment (reduced dependence)	310	96	22 – 34	9
Best case no. of people who will be harmed from treatment (symptomatic intracranial bleeding)	0	13	22	1.5

Notes

a: In NZ, the most recent survey of rehabilitation services took place in 2014. The DHBs which have organised stroke care in place have a catchment area of 62% of NZ's total population (McNaughton, McRae, Green, Abernethy, & Gommans,

2014). Therefore, best case scenario of NZ people with stroke eligible for organised stroke care is estimated to be 62% of the total number of persons with stroke.

b: Only people with ischaemic stroke (approximately 85% of all stroke in NZ) are eligible for treatment with aspirin.

c: Between 5 – 15% of all people with stroke screened in randomised controlled trials were deemed eligible for IV thrombolysis (Buchan et al., 2000; IST-3 collaborative group et al., 2012).

d: Based on ARCOS data, 5% of people with ischaemic stroke received IV thrombolysis. This figure, while representative only of people with stroke within the Auckland Region, has been extrapolated to 5% of all ischaemic strokes in NZ (Feigin, Krishnamurthi, Barker-Collo, et al., 2015).

e: NNT to prevent death and dependence and NNH from Cochrane systematic review (Wardlaw et al., 2014).

F: REVASCAT was the only large randomised controlled trial to accurately report the number of people with stroke in their catchment who were screened for eligibility and the number who underwent thrombectomy (Jovin et al., 2015). 540 people with stroke underwent thrombectomy out of 17596 people with stroke on their registry. Those on the registry were 15% of all people with ischaemic stroke in Catalonia.

g: From the same study above, approximately 3% of all people with ischaemic stroke in Catalonia underwent thrombectomy (Jovin et al., 2015). These figures occurred in the setting of a randomised controlled trial, where participating sites were high volume stroke centres, and neuro-interventionalists performed more than 60 ECRs per year. The figure of 3% has been extrapolated to 3% of all ischaemic stroke in NZ, but in reality this would only apply to the metropolitan centres of Auckland, Wellington and Christchurch.

h: NNT and NNH based on systematic review of six pooled ECR trials (Hussain et al., 2016).

The overall impact of tPA and thrombectomy is insufficient to mitigate or manage the problem of increasing stroke incidence in New Zealand and globally. From a public health perspective, these treatments are limited by their restrictive eligibility criteria, high cost, and a safety profile that is not without potential for significant harm.

In reality, the majority of people with stroke are discharged to community living with varying levels of activity limitation and functional dependency. Although new interventions are available, due to inadequate primary prevention and the aging population, the number of people affected by stroke living in the community will continue to grow. In middle to high-income countries, people with stroke may have access to therapy-led rehabilitation, although availability, content, and the amount and frequency of contact received will vary between countries.

Next, we shall consider what happens to people with stroke after they leave the care of the acute stroke team. This next phase is commonly known as rehabilitation. Usually, rehabilitation assessments begin as soon as the patient is medically stable, however, not all people with stroke receive extensive inpatient rehabilitation. Some people with stroke may be so disabled by stroke that they are discharged to institutional care. Others may be discharged directly home because their impairment is assessed to be mild. In both scenarios, the feeling is that rehabilitation will be of limited benefit to the person with stroke. Allocation of limited resources by clinicians and managers includes deciding who may benefit most from certain treatment. Compared to 30 years ago, the mean (SD) length of stay in hospital has halved from 30.5 (27.2) days in 1997 to 15.7 (20.5) days in 2013 (Joshi, P; Wong, L; Weatherall, M; Lanford, J; Fu, V; McNaughton, 2015).

The largest group of people with stroke are those who are discharged home, either directly from the care of the stroke team or from inpatient rehabilitation, who return to live in the community. The following chapter will review the literature of current

interventions for this category of people with stroke. It is necessary to examine these interventions because the outcomes for this group have remained static over past decades. Of particular concern is that some people who were initially independent at the time of discharge deteriorate at home over time, becoming dependent or requiring institutional care by 9-12 months after the index stroke (McNaughton et al., 2011). This is a worrying signal that current community interventions are not sufficiently preventing deterioration.

2.2   Outcomes in people with stroke living in the community

In the previous section, evidence regarding the proportions of people with stroke expected to have predicted medium and long-term physical outcomes was presented. To recap, roughly 80% of people with stroke will survive to be discharged from hospital. 20% of these people are discharged directly to institutional care, either a rest home or hospital level care, because of dependency. For the remainder who are discharged home, about a third are dependent on others for activities of daily living (ADL). Figure 1 illustrates the proportional distribution of outcomes for 100 people with stroke. The numbers of each outcome are estimates based on outcome studies conducted in New Zealand.

By nine months after stroke, the mortality rate increases to 30%, and those dependent on others for ADL increases to 40%. These proportions are derived from longitudinal stroke studies within Aotearoa New Zealand, remaining as true to the situation of the New Zealand health care system as possible. The annual stroke incidence in Aotearoa New Zealand is estimated to be between 7000-9000 ("Facts and fallacies | Stroke Foundation of New Zealand," n.d.; Feigin, Krishnamurthi, Barker-Collo, et al., 2015). Figure 2 shows the estimates of outcomes of the same group of people with stroke at 9 – 12 months.

ADL come under the ICF category of 'Impairment', or how an individual interacts with their immediate environment. These ADL may include caring for oneself such as eating, dressing, and washing, as well as mobilising or being able to walk around. Because 'Impairment' is only one level within the ICF, it is important to remember that those who are not dependent for ADL may still experience other consequences from their stroke and not be fully recovered.

Figure 1. Estimation of outcomes at discharge of 100 people with stroke
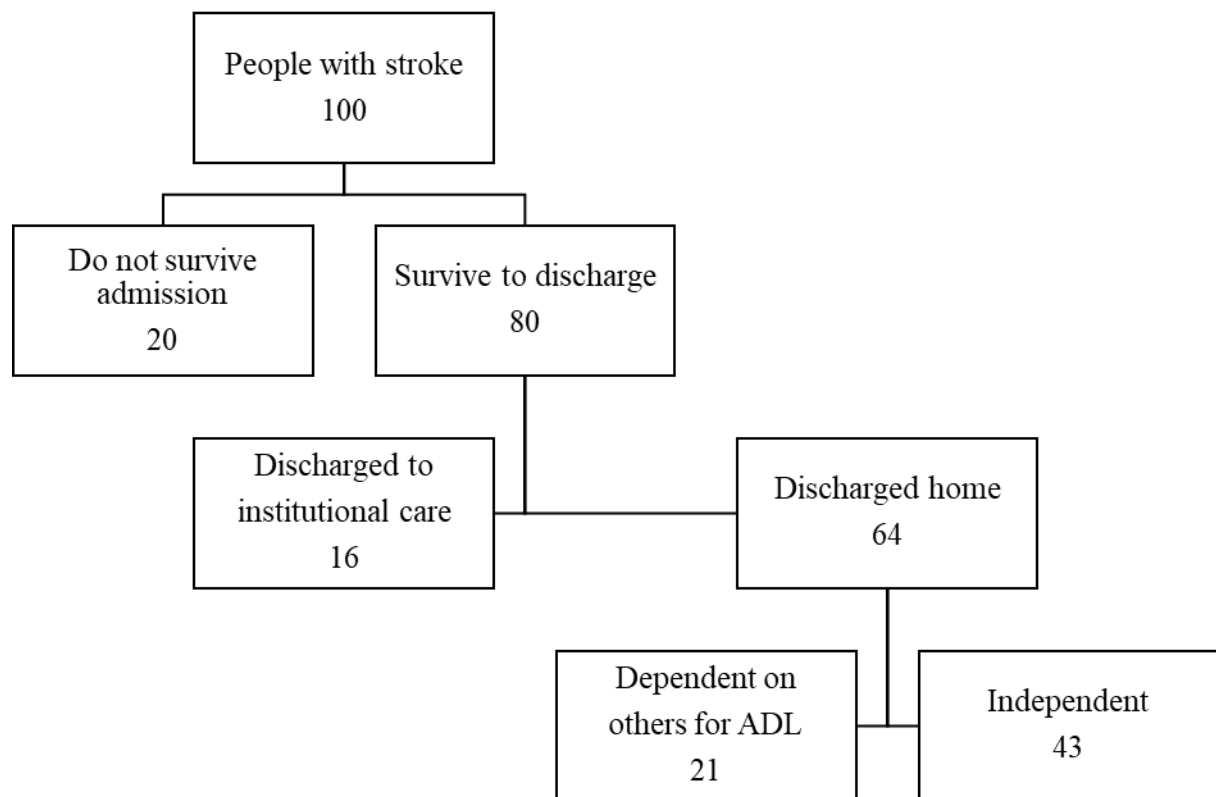
Figure 2. Estimation of outcomes 9 - 12 months following stroke for the same 100 persons with stroke

```
                    ┌─────────────────────┐
                    │  People with stroke │
                    │         100         │
                    └──────────┬──────────┘
              ┌────────────────┴────────────────┐
    ┌─────────────────┐               ┌─────────────────┐
    │      Dead       │               │      Alive       │
    │       30        │               │       70         │
    └─────────────────┘               └────────┬────────┘
          ┌───────────────────────────┐   ┌─────────────────┐
          │       Living in           │   │  Living at home │
          │   institutional care      ├───┤       50        │
          │          20               │   │                 │
          └───────────────────────────┘   └────────┬────────┘
                   ┌─────────────────┐     ┌─────────────────┐
                   │  Dependent on   │     │                 │
                   │ others for ADL  ├─────┤  Independent    │
                   │        8        │     │       42        │
                   └─────────────────┘     └─────────────────┘
```
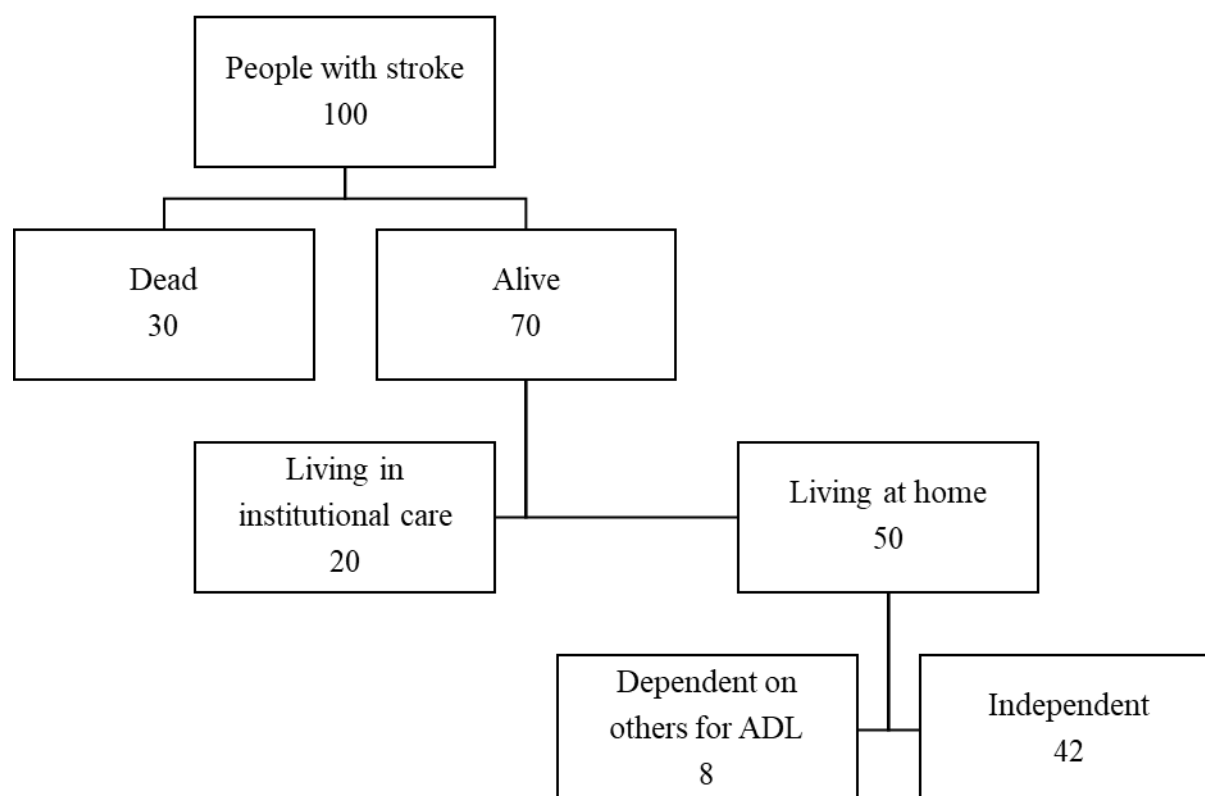
Translating the proportions into actual numbers of people with stroke in New Zealand provides a clearer perspective. To do so, the larger of the estimates - 9000 - will be used, due to the aforementioned predicted increase in stroke prevalence worldwide. In numerical terms, therefore, each year over 7000 people will survive their initial admission for stroke. Over 1000 people with stroke will be discharged to institutional care. The remainder will return to community living, but nearly 2000 people with stroke are dependent on another person for ADL every year in New Zealand. The main carer may be a spouse, a child, a friend, or a private carer. Almost 4000 people with stroke will be independent with their ADL but may not be fully recovered from the stroke. Ongoing,

significant problems include post-stroke fatigue, cognitive impairment, and not being able to participate in social or family life.

Within the first year after stroke, the outcomes of people with stroke worsen. Every year, nearly 3000 people in New Zealand die within the first year of their stroke ("Facts about stroke in New Zealand," n.d.). The number living in institutional care increases to almost 2000. These people may have deteriorated in their own environment, or experienced complications or other medical conditions that led to needing the help of others at a nursing home. Of the remaining 4500 people who are still living at home at one year, almost 720 are dependent on others for ADL. Of the original 9000 people with stroke, only 3,750 of them remain living in the community independently at one year .

Increasing dependency

Why do more people with stroke living in the community become dependent over time? The reasons are not entirely clear, even though the numbers and proportions of long-term outcomes after stroke have been well-proven and reproduced in other studies. I will now explore the possible explanations for this deterioration.

As mentioned earlier, there are predictable medical complications of stroke. The most common complications are infection, due to aspiration pneumonia or urinary tract infection, and falls causing injury. The natural history of stroke is related to cardiovascular risk factors, such as hypertension, diabetes, and ischaemic heart disease. A person with stroke has an increased risk of having a second stroke, even if risk factors are treated. Furthermore, stroke can also herald underlying cancer which causes a hypercoagulable state (Pamela W Duncan et al., 2005).

However, medical complications cannot account for all of the deterioration we observe. It is worth asking the question – what happens after a person with stroke returns home? Does motivation drop? Might a stroke survivor, like most human beings, be unable to maintain behavioural change? Are we satisfied that current outpatient rehabilitation services are adequate to meet the ongoing needs of people with stroke and their families? How many people give up because they lose hope of ever regaining an acceptable quality of life?

The consequences of this increase in dependency is not only a financial cost to the person with stroke (especially if employment is terminated), but also includes increased physical and emotional strain for caregivers. Some families prioritise the importance of keeping their loved ones living outside of institutional care. The benefits include preserved physical and mental wellbeing of being able to keep an older person living in their own, familiar space, with autonomy. To realise these benefits, next-of-kin and carers may have to choose to make significant sacrifices. For example, adult children may give up their employment or sell their assets to move in with their parent(s) who have had a stroke to provide them with necessary care.

The increase in dependency also causes rising cost burden to the public health system and society in general. A spouse or next-of-kin can provide care, but they are not financially recompensed. They are also removed from a working position that contributes to the overall economy of society.

If no carer was available, a person with stroke could access publicly funded care support through private companies that have contracts with DHBs to provide community care. However, when a person becomes increasingly dependent, this care may not be adequate to meet an individual's high needs and the person may need to move into an assisted living facility. For example, additional care is needed if a person develops incontinence,

and publicly funded care support can only, at best, provide home visits to help with personal cares twice daily, seven days a week. If the individual qualifies by passing a test of their financial assets, the New Zealand government (through the Ministry of Health) subsidises the cost of their institutional care as a top-up to the overall cost charged by the private care facility (Ministry of Health Manatū Hauora, n.d.).

Furthermore, especially for younger persons with stroke, the transition from being 'independent but not fully recovered' to being 'dependent' may translate practicably to other major life changes such as the losses of employment, social connections and hobbies, the inability to care for their family, the inability to drive, increasing isolation, and depression (Synhaeve et al., 2014). The social and psychological impact of a stroke can be immeasurable and far-reaching.

It is imperative, therefore, not to lose sight of the greater problem. The impact of a stroke on a person's life is far more substantial than physical disability alone. Functional recovery from a stroke takes months to years, and already we have seen that the proportion of people who become dependent increases over a short time within the first 12 months following stroke. There is a window of opportunity in which this predicted path may be modulated. We must continue to investigate ways to improve outcomes in people with stroke living in the community.

The following section is a literature review that describes the large-scale rehabilitation interventions that have been studied in community stroke, some of which have been trialled in clinical practice and some which remain in use today.

2.3   Interventions for community people with stroke

This section will review the literature for existing stroke rehabilitation interventions that are either in use or have previously been used but later shown to be ineffective. These include therapy-based interventions (such as outpatient physiotherapy, occupational therapy or the use of outpatient multi-disciplinary teams), stroke liaison workers, the setting of rehabilitation goals, and self-management interventions. The use of caregiver-led rehabilitation was also investigated and published during this thesis. Caregiver-led rehabilitation was a novel intervention approaching therapy-led rehabilitation in a slightly different way and the results were relevant to the argument that therapy-based interventions lack convincing evidence for their effectiveness. This study will, therefore, be included as an addition to the literature review.

Furthermore, due to the breadth of literature available in the field of stroke rehabilitation, where available, systematic reviews were included in place of individual studies. The former was chosen because a meta-analysis theoretically provides the highest level of evidence about a particular subject. Interpretations of results will be provided, including critiques of conclusions by the authors of individual studies and reviews.

2.3.1   Therapy-led rehabilitation

The Clinical Guidelines for Stroke Management recommend that 'community-dwelling stroke survivors with confirmed difficulties in personal or extended ADL should have specific therapy from a trained clinician to address these issues' (Stroke Foundation, 2017). Based on my clinical experience, the most common form of intervention used in the community stroke population is outpatient rehabilitation by trained therapists. In

New Zealand, these therapists include physiotherapists, occupational therapists, speech language therapists, and their assistants, and they form part of a multi-disciplinary team. Some teams may include a rehabilitation physician or community geriatrician, and a social worker.

For the most part, the therapy is led usually by a physiotherapist or occupational therapist, depending on the perceived needs and goals of the person with stroke. They may issue specific equipment or walking aids and recommend home modifications, such as the installation of handrails. If a person with stroke is deemed to be eligible for outpatient rehabilitation after discharge, the team or therapist usually visits them at home and conducts further assessments of how they are managing. They may prescribe exercises, or teach compensation techniques, or accompany the person on a walk. Figure 3 shows intervention strategies employed in therapy-based rehabilitation relative to the hypothetical pattern of recovery.

The quality, quantity, and intensity of the rehabilitation that a person receives are dependent upon the expertise and opinions of the different therapists. A less common type of outpatient rehabilitation is group therapy, which is usually held at a local gymnasium or hall and is run by a therapist. Community people with stroke may have difficulty with transport or be legally prohibited from driving; therefore, it is uncommon for group therapy to be a sole mode of rehabilitation.

Given the ubiquitous nature of outpatient therapy-based rehabilitation, it is essential to review its effectiveness at improving outcomes after stroke. As its use is considered routine, and the public health system funds it, a presumption is held that outpatient, therapy-led rehabilitation is effective at improving outcomes for people with stroke. This chapter will review a Cochrane systematic review of outpatient, therapy-led

rehabilitation, followed by a New Zealand-based qualitative study exploring insights of three therapists in the way they practise.

Figure 3. Hypothetical pattern of recovery after stroke with timing of intervention strategies.[1]
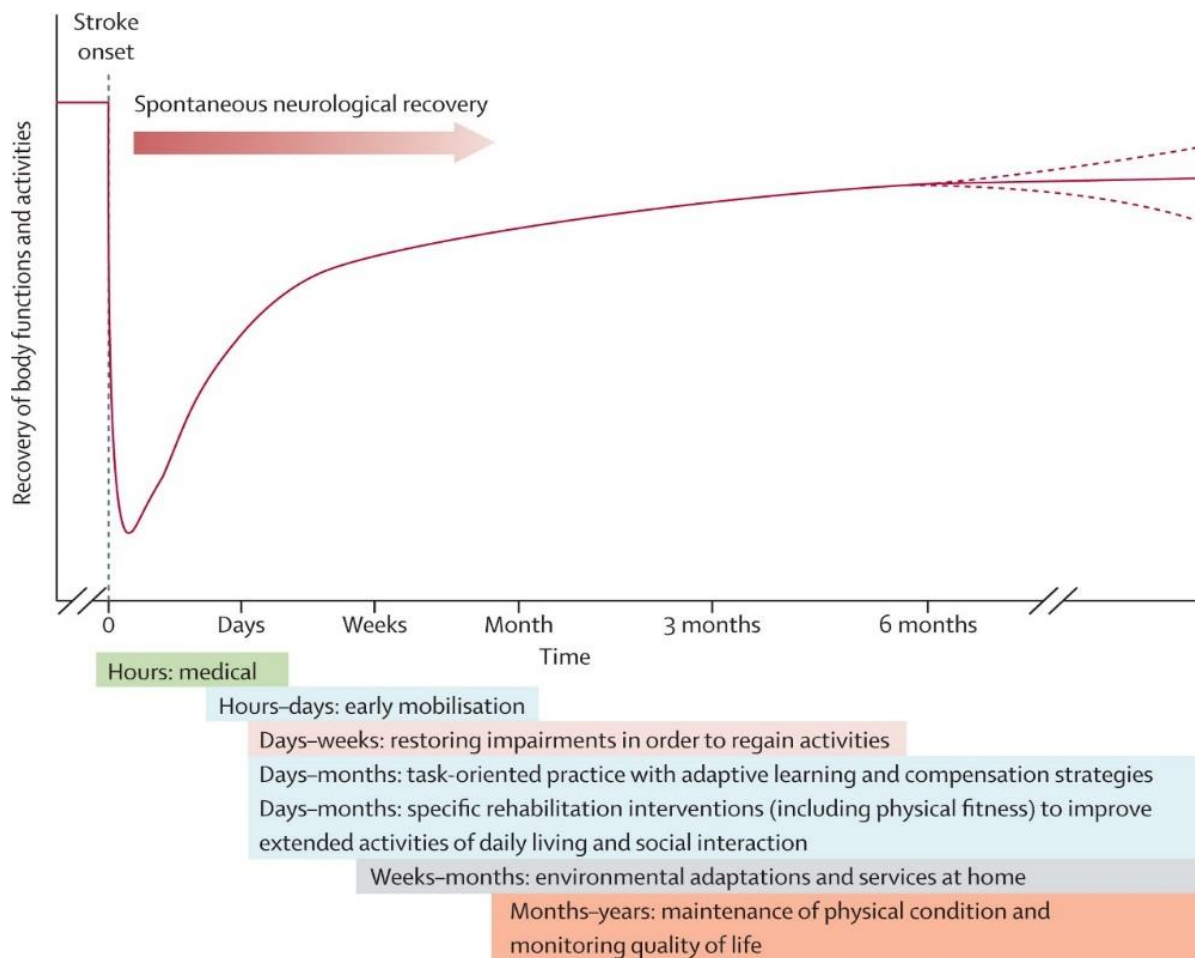
1. Reprinted from The Lancet, Vol 377, Langhorne, P; Bernhardt, J; Kwakkel, G; Stroke Rehabilitation, p. 1693-1702, Copyright 2011, with permission from Elsevier.

Cochrane systematic review of therapy-led rehabilitation

One of the most comprehensive quantitative analyses of therapy-led interventions is the systematic review conducted by the Outpatient Service Trialists for the Cochrane database (Outpatient Service Trialists, 2003). The objective of this systematic review was to address three main questions:

1) Can therapy-based rehabilitation services exert any beneficial effect on the outcomes of people with stroke (and those of their carers)?

2) Which components of such services are effective (e.g. physiotherapy, occupational therapy, multidisciplinary)?

3) Which outcomes are influenced (e.g. dependency, social activities, mood, or functional deterioration)?

The review only included randomised controlled trials comparing outpatient, therapy-based interventions with a control group (Outpatient Service Trialists, 2003). The interventions had to be tested at a service level rather than at the level of specific interventional techniques, and the study aim had to specify delivering the intervention to a large group of stroke patients with broad casemix, rather than to specific subgroups.

14 studies were included in the analysis, comprising 1617 patients. Complete data were available for 1479 patients. Patients had to fulfil a clinical diagnosis of stroke, be residing in a community setting, and randomised in their study within one year of index stroke. The mean age of participants ranged from 55 to 75 years. Stroke severity in the form of baseline Barthel Index (BI) was reported in four studies, and median BI in intervention and control groups was 18. One study excluded patients with a history of stroke, seven studies excluded patients with communication or cognitive difficulties which were predicted would interfere with participation in treatment or outcome

assessments, five studies excluded people who were non-English-speaking, and two studies excluded people who were terminally ill.

The interventions were described as domiciliary therapy programmes, home-based exercise programmes (to improve strength and balance, and to encourage the use of affected extremity), education programmes, information provision, practising dressing techniques, and practising techniques to conserve energy. Some studies specified that the amount of therapy delivered was at the therapist's discretion. Other studies randomised participants to a leisure group and others to a pure ADL group, in which goals were set in both groups but the leisure group 'focused on ADL tasks needed to achieve leisure objectives'.

Nine studies described the intensity of their interventions. Four studies tested a programme that lasted six months, and another had a programme that lasted five months with a mean of 5.6 visits per patient. Other studies had programmes that ranged from five to nine weeks. Visits tended to be anywhere between 30 to 90 minutes long. Those allocated to the comparison group received routine/usual outpatient care.

Median follow-up was six months but ranged from three to 12 months. There were a variety of outcome measures, but several were common. Due to the heterogeneity of instruments used between studies, the authors of the systematic review limited their analysis to patient outcomes: death, death or requiring institutional care, death or dependency, death or a poor outcome (deterioration, dependency, or requiring institutional care), personal ADL (mostly using the Barthel Index if this was reported or an alternative scale), extended ADL (using the Nottingham Extended Activities of Daily Living Index or an alternative scale), quality of life (Nottingham Health Profile or an alternative scale), and mood (General Health Questionnaire).

Therapy-led interventions had no effect on death (odds ratio (OR) 1.10, 95% CI 0.76 to 1.59, p = 0.6). Death data were available for 91.5% of patients. Data of the combined outcome of 'death or requiring institutional care' were only available for 37% of patients. The summary OR for this outcome was 0.81 (95% CI 0.54 to 1.21, p = 0.3). This was not statistically significant.

For this systematic review, 'dependent' was defined as Barthel Index of less than 15, which was a pre-determined cut-off score. Data from 58.3% of patients were available for the combined outcome of 'dead or dependent'. It is unclear whether this score was pre-determined by the individual studies' investigators or by the authors of the systematic review. However, in other stroke literature, when the Barthel Index is used as a measurement of dependence, BI < 15 is considered 'severe dependence', while BI 15-19 is categorised as 'mild to moderate dependence' and BI 20 is independent. It seems unusual that the category of mild to moderate dependence was overlooked. Nevertheless, therapy-led rehabilitation had an odds ratio of 0.93 for death or dependence, which was not statistically significant (95% CI 0.77 to 1.22, p = 0.6). In other words, receiving outpatient therapy-led interventions did not affect the outcomes of death, institutionalisation, and dependence.

The fourth statistical analysis was, therefore, a bit difficult to unpack. The authors combined the outcome of 'death' with that of 'deterioration', determined by a drop in the Barthel Index score. Statistically, one might argue that they continued to include 'death' in the analysis because it was the worst possible outcome, and doing so helped to boost the numbers so that the analysis had greater power. Despite this, data for the 'death and deterioration' analysis were only available for 33.9% of the total patients, and from this, they were able to derive an odds ratio of 0.67 of death or deterioration in those who received therapy (95% CI 0.46 to 0.97, p = 0.03). If 'death' had been removed from the

analysis, the number of patients included in the analysis of simply 'deterioration' would have been far fewer, and the difference is unlikely to have been statistically significant.

The investigators' justification for including 'death' in the statistical analysis was to ensure that a reduction in 'deterioration' was not occurring at the expense of increased mortality. The effect size of this 'deterioration' was estimated to be equivalent to one point on the BI score. This effect is minimal and clinically insignificant. Using the event rate of 37.5% in the control group, they calculated an NNT of 14 people to prevent one person from dropping one point on the BI.

For many years, the general consensus was that a change of 4 points on the BI was considered to be clinically significant for people with neurological disease (D. Wade, 1992). A more recent study using anchor-based and distribution-based methods in Taiwanese people with sub-acute and chronic stroke found that the minimal clinically important difference (MCID) for the BI was 1.85 for improvement (Hsieh et al., 2007). No studies have evaluated the MCID for deterioration in BI.

Furthermore, the authors then combined the data with that available for 'dependency' and 'institutionalisation', forming a new analysis termed 'death or poor outcome'. Pooling the outcome data allowed analysis of 83.5% of total patient data, thus increasing power. This produced an OR of 0.72 (95% CI 0.57 to 0.92, $p = 0.009$) and the conclusion that therapy-based rehabilitation significantly reduced the odds of 'death or poor outcome'.

My interpretation is that these latter two analyses, 'death or deterioration' and 'death or poor outcome', even if they were pre-specified, need to be interpreted with caution. The investigators had already shown that there was no significant difference between therapy and control for each of these outcomes individually. It is not uncommon for a

significant P-value to be found when a large number of statistical tests are run with multiple adjustments for potential confounding variables.

Furthermore, in drawing these conclusions, the authors acknowledged that no 'formal statistical testing was done', and that the effect sizes were larger in the studies that had poor methodology (including unclear procedures for randomisation and allocation concealment). When these two large studies were excluded from the analysis, the perceived beneficial effect of therapy was more modest, producing an OR of 0.75 (95% CI 0.58 to 0.97, $p = 0.01$). Also, when the authors limited the analysis to the studies which had a clear intention to treat analysis, the odds of a poor outcome were higher, OR 0.80 (95% CI 0.58 to 1.09, $p = 0.16$) and no longer significant.

Analysis of personal ADL alone did show a weak positive result. Data were available for 73% of the patients. The pooled result for all the trials, combined using a standardised mean difference (SMD) with a random effects model was 0.14 (95% CI 0.02 to 0.25, $p = 0.02$). However, this effect was reduced when the analyses were restricted to the studies which had adequate blinding, and the studies which had a clear intention-to-treat analysis.

Similarly, analysis of extended ADL showed a modest positive result. Fewer patients (61.6%) had available data for analysis. The pooled result of all the trials, using the method above, was 0.17 (95% CI 0.04 to 0.3, $p = 0.01$). Therapy-based rehabilitation had no effect on quality of life.

The most obvious point that emerged from this systematic review was that there were no significant differences for main pre-planned outcomes between patients who received therapy-led rehabilitation and those who did not. There is a speculative and statistically questionable reduction in the BI score, by an amount which is not clinically significant.

It is, therefore, concerning that the authors concluded with this statement: "*Therapy-based rehabilitation services reduces the odds of a poor outcome, i.e. death or deterioration in ability to perform activities of daily living, and has a beneficial effect on a patient's ability to perform personal activities of daily living and extended activities of daily living. Approximately 13 patients need to be treated to prevent on avoidable deterioration.*" They also write that: "*…the debate should move from whether such services are effective*", as though this analysis has unequivocally proven effectiveness, the question no longer requires interrogation, and the matter should be laid to rest.

A more candid conclusion for this critical systematic review is suggested. Therapy-based rehabilitation services may increase the odds of independence in extended activities of daily living, and reduce the odds of a deterioration in the ability to perform personal activities of daily living. Effect sizes are reduced when analyses are limited to the studies that were of high quality (adequate blinding, clear intention-to-treat analysis). 14 people need to be treated with therapy-based rehabilitation to prevent one person from dropping one point on the BI.

However, there are several important points to contemplate. First, therapy-led rehabilitation is a costly, labour-intensive intervention for the amount of benefit it may actually deliver. Second, one might wonder whether therapy-led rehabilitation given at its 'usual doses' may not be effective, and an increase in the 'dose' of therapy might show a greater effect size. Unfortunately, most therapy-led rehabilitation methods used in randomised controlled trials are more structured than routine practice and use much higher doses, and a trend to better outcomes simply is not seen. Third, given that therapy-based rehabilitation has been tested in a number of different trials, it should be straightforward to design a high-quality, randomised controlled trial to confirm whether or not therapy-based rehabilitation is effective.

If meta-analysis of so many trials has not convincingly shown moderate to large, positive effect sizes in meaningful outcomes, which are reproducible, then one has to question what it is we are actually doing in routine clinical practice. Why are we willing to accept that what is being delivered in rehabilitation is full of so many unknowns? Rehabilitation researchers themselves have coined the term 'the black box of rehabilitation' to describe this phenomenon (DeJong, Horn, Conroy, Nichols, & Healton, 2005; Derick T Wade, 2001). The term 'black box' refers to a device, system, or object which can be viewed in terms of its inputs and outputs (or transfer characteristics), without any knowledge of its internal workings.

What is clear is that because of its complexity, unpacking the 'black box' of rehabilitation' needs to be aided by qualitative research. Experiencing stroke and rehabilitation are subjective, and as much as researchers might think they are capable of empathy, their views cannot truly reflect those of people with stroke. Rehabilitation *does do something* for people with stroke, because one can surmise that life would be worse for people with stroke if rehabilitation did not exist. How rehabilitation benefits people with stroke is not well understood, perhaps in part due to the bluntness of objective, quantitative measures such as the mRS. Better understanding requires the insight of those directly involved (clinicians and people with stroke) for the 'black box' to be adequately unpacked.

Qualitative study of therapy-led rehabilitation, by therapists
An introspective, qualitative study by three therapists in Aotearoa New Zealand revealed significant insights that were new to them. In describing them, these therapists acknowledged that such insights were not likely to be apparent to most rehabilitation practitioners (Bright, Boland, Rutherford, Kayes, & McPherson, 2012). As part of a larger, randomised controlled trial of goal-setting in traumatic brain injury, the therapists performed an autoethnographic study in which they wrote, discussed, reflected, and

analysed their experiences multiple times. Their notes and discussions were coded, analysed and the study stopped when themes were saturated.

The three therapists initially reflected upon where they came from and the clinical contexts in which they previously worked. They noted that the priorities of the health system dramatically influenced how therapists prescribed and provided rehabilitation. The pressures of rapid discharge from hospital and funding issues led to a 'tick-box mentality', with a reductionist focus on process. This mentality resulted in the therapists' perceptions being influenced by what they considered to be 'un/realistic given the demands of the service'. This mentality also limited what was explored or enabled when setting goals and talking about expectations for the future with patients.

The therapists realised that the dominant model of care was paternalistic, 'assessment-based and deficit-driven'. Their work focused on what patients could not do. The resulting relationship with patients was one which prioritised the need to 'assess, prescribe, and treat.' In undertaking this auto-ethnography, the authors felt that in the past they had missed vital information about what was most important to their clients, what was meaningful, and how they saw themselves in the light of their injury/illness.

Four major themes evolved out of these discussions. These were: (1) seeing active and mindful listening as a therapeutic tool; (2) the importance of allowing time; (3) supporting clients to prioritise what is meaningful; and (4) viewing the therapist's role differently to how they had viewed it before this study. Their approach to client-centred care was novel. Most practitioners still work within the limits of the health system and the medical model of care, but this paper was revealing in that it distilled a different way of thinking about rehabilitation, and how honestly facilitating patient-centred care might lead to a more satisfying and engaging experience for therapist and patient.

This study revealed important insights from therapists about the work that to they do, and in particular the factors that limit the effectiveness of their work with patients. They revealed an important insight, that goal setting and discussions about expectations in the future were limited by a tick-box mentality. This is concerning, because goal setting is commonly used in rehabilitation, and it provides a framework from which patients and therapists think about and proceed with their rehabilitation. The following section will evaluate the evidence about goal setting for people with stroke in the community.

2.3.2   Quantitative studies in goal setting

Goal setting forms the core of most rehabilitation programmes, not only in stroke but also in other health conditions. One proposed definition of a rehabilitation goal is 'a future state that is desired and/or expected. The state might refer to relative changes or to an absolute achievement. It might refer to matters affecting the patient, the patient's environment, the family or any other party. It is a generic term with no implications about time frame or level' (Derick T Wade, 1998). Wade also proposed that goal setting referred to 'the process of agreeing on goals', which is routinely employed as a technique by therapists in inpatient and outpatient settings. However, there is significant variability in the many components of how goal setting is done.

These variables include:
- choosing goals (e.g. who is involved; how goals are identified and prioritised);
- goal characteristics (i.e. how goals are written; whether they need to be phrased a certain way, using particular language);
- goal content (i.e. what is considered an acceptable topic for a goal; whether goals need to be set at a particular level of the ICF);

- how goals are used in clinical settings (e.g. the way goals are used in team meetings with patients; how feedback on progress toward goals is presented to patients and the team); and
- the intended purpose(s) of setting and having goals.

Over the years, people have developed different methods and ways to think about goals. For example, the SMART (Specific, Measurable, Achievable, Realistic, Timely) framework for setting goals was first introduced in a business magazine, but is now ubiquitous in any discussion or instruction about goal setting, including in education (Doran GT, Miller AF, 1981). Of late, rehabilitation literature has recognised that such acronyms have their own limitations, therefore, they are recommended to be used only as a guide. Wade wrote that 'there is much room for interpretation of how these goals should be set' (D. Wade, 2009).

Furthermore, the field of psychology has extensively explored the importance of goals to human beings and their behaviour. Some of the theories developed from psychology have been recognised as being relevant to rehabilitation goal setting, because these theories describe how people use goals to monitor and change their behaviour (Scobbie, Wyke, & Dixon, 2009). They also describe how perceptions of illness and the effects of interventions can influence behaviour, and how effects of goals can be moderated by other factors. These include the individual's level of personal commitment, their belief in their ability to achieve the goal (self-efficacy), how complex the goal or task is, and the way goals are presented or worded.

In clinical practice, it has also been found that other factors mediate the importance of the goal to the person. These include how meaningful the goal is to the patient (i.e. whether they reflect higher-value desires), how involved the patient is in the process of

selecting their goals, whether the goal is termed 'reasonable' or 'realistic', and how involved family members or significant others are in the process (Wilson, 2008).

Goal setting is thought to improve patient outcomes by:

- increasing motivation to participate in rehabilitation;
- improving teamwork and forming a common language for use between the patient, their family, and the rehabilitation team;
- directing instructions to be more specific;
- enhancing patient self-determination and autonomy; and
- providing feedback by determined levels of goal attainment.

Goal setting is commonly employed as a key component within the broader scope of rehabilitation. In some health care settings, goal setting has become a contractual requirement of service delivery. Furthermore, in Aotearoa New Zealand, it is common for therapists to transition between specialities and very few train solely in neuro-rehabilitation in the public sector. Therefore, goal setting used by therapists is more likely to be of a nature that is used with patients with health conditions and disabilities other than stroke.

Cochrane systematic review of goal setting

Levack and colleagues conducted a Cochrane systematic review of goal setting for adults with disability (acquired after the age of 16) participating in rehabilitation (W. M. M. Levack et al., 2015). They included 39 studies (27 RCTs, six cluster-RCTs, and six quasi-RCTs) involving 2846 participants. The clinical context of these studies was wide-ranging, as were the included patients' primary health conditions. The most common health conditions were musculoskeletal disorders, brain injury, chronic pain, mental health conditions, and cardiovascular disease. The term 'strategy for goal pursuit' refers to **how** progress towards goals is shared, communicated and used.

Included studies investigated any of the following:

Number of trials	Exposure	Comparator
18	A structured approach to goal setting ± strategies for goal pursuit	No goal setting
14	A structured approach to goal setting ± strategies for goal pursuit	Usual care, which may have included goal setting that was not structured
2	Interventions to enhance goal pursuit	No interventions to enhance goal pursuit
9	One structured approach to goal setting ± strategy for goal pursuit	Another structured approach to goal setting ± strategy for goal pursuit

The primary outcome measures were:

- Health-related quality of life or self-reported emotional status,

- Participation outcomes as defined by the ICF (e.g. work, community integration, social relationships), and

- Activity outcomes as defined by the ICF (e.g. functional activities of daily living, mobility).

There were eight studies (448 participants) which compared goal setting ± strategies to enhance goal pursuit, to no goal setting. These studies provided very low quality evidence that use of any goal setting in adult rehabilitation increased health-related quality of life / self-reported emotional status compared to no goal setting (standardised mean difference (SMD) 0.53, 95% CI 0.17 to 0.88). This outcome was most commonly

measured using the mental component summary score (MCS of the SF-36) of the Short Form 36-item questionnaire.

Four studies reported measures that were at the level of social participation as defined by the ICF, but the measures were too dissimilar to be meta-analysed. However, all of the studies reported no difference in work performance or satisfaction with occupational performance between the goal setting and the no goal setting groups.

Four studies (223 participants) reported activity levels as defined by the ICF. The meta-analysis showed no difference in activity levels when some form of goal setting was used compared to no goal setting (SMD 0.04, 95% CI -0.22 to 0.31). There was no evidence of statistical heterogeneity in the outcomes.

Nine studies (369 participants) reported patient engagement in rehabilitation. When standard effect sizes were pooled, the meta-analysis showed no difference in patient engagement in rehabilitation between goal setting and no goal setting groups (SMD 0.30, 95% CI -0.07 to 0.66).

Three studies, with a total of 108 participants, provided very low quality evidence for improvement in self-efficacy in those who received goal setting (SMD 1.07, 95% CI 0.64 to 1.49). Structured goal setting also improved self-efficacy compared with usual care (which may have involved goal setting in an unstructured way) (SMD 0.37, 95% CI 0.02 to 0.71).

In this systematic review, goal setting did not improve social participation or activity levels or levels of patient engagement in the rehabilitation process, compared to no goal setting. Data were insufficient to determine whether goal setting led to a difference in adverse events. At best, this systematic review was able to find very low quality evidence

that goal setting might improve some psychosocial outcomes (of self-perceived self-efficacy and health-related quality of life) for adults receiving rehabilitation for acquired disability.

The wide range of clinical contexts and health conditions included in this systematic review may have exacerbated the inconclusive nature and poor quality of the results. Not only were the conditions heterogeneous (i.e. musculoskeletal disorders, mental health conditions and cardiovascular disease), but defining and aligning all the various goal setting methods tested by the different studies would have been very difficult.
For example, using goal setting as a strategy would produce markedly different endpoints and desired effects in the rehabilitation of patients with long-term, chronic conditions (such as chronic pain, arthritis, or diabetes), compared with those who experience a sudden, debilitating event (such as stroke, traumatic injury, or myocardial infarction). The immediate sense of direction and focus that goal setting might provide following a sudden health event is different to that of someone who may be setting a goal to remain engaged with behavioural modification. Examples of behavioural modification include self-monitoring, adherence to medications, or participating in an exercise programme. Combining and analysing all health conditions and their different reasons for goal setting would likely have diluted the potential impact of goal setting for those with a suddenly acquired disability.

Despite this criticism, a moderately large systematic review based on available evidence has provided weak evidence that goal setting improved health-related quality of life and self-efficacy. The effect size for the improvement in health-related quality of life is small. There was no evidence that goal setting improved participation, activity, or engagement with rehabilitation. Perhaps the more disheartening finding from this review was the fact that setting goals did not appear to change how hard participants tried during rehabilitation.

The Māori and Pacific Stroke study (MaPSS), the study which first identified a positive effect from the Take Charge intervention, was included in this Cochrane systematic review. This was because goal setting formed the second component of the Take Charge session (Section 2.5.1, page 100). Participants who received the Take Charge session showed a statistically significant improvement in activities of daily living and dependence (M. Harwood et al., 2012).

There are two plausible explanations for this. Both are distinct possibilities on their own, but could also be occurring simultaneously. First, it is possible that the first component of the Take Charge session, which explores and validates a person's sense of self, caused most of the improvement effect at the level of social activity and participation. Alternatively, perhaps the distinct method by which the goals were reached played a role. Goal setting in the Take Charge session was undertaken solely by the person with stroke without input or suggestion from the research clinician. It is possible that this novel, person-centred approach may have contributed to the Take Charge session's effectiveness at improving higher-level outcomes. We hope that the results of the present study, the Taking Charge After Stroke (TaCAS) study will shed further light on this approach.

The authors of the systematic review concluded that further research was needed to understand how components of the goal setting process contribute to health outcomes. Given the heterogeneity of the trials, it is notable that an effect was seen for goal setting at the level of health-related quality of life. Therefore, one would hesitate to write off goal setting altogether. The quality of available evidence is of low quality, and it is very likely that goal setting, even when done consistently, is wanting in its person-centredness, timeframe and relevance. The TaCAS study may contribute further to evidence for, or against, the use of goal setting.

Aside from the main problem of heterogeneity, one could speculate on other reasons why the evidence for goal setting was so weak in quantitative studies. First, it has been proposed that goals set at the ICF levels of activity and social participation are more likely to be successful than goals set at the level of body structure and function (Randall & McEwen, 2000). Based on personal clinical experience and observation, this principle is often not followed by health professionals. The reason that clinicians are unlikely to adhere to this principle is due to the conflict that arises when the reasons for goal setting are different for different parties. For example, in situations where achievement of goals may be used as a measure of the efficiency of a rehabilitation service, health professionals may be less likely to support or agree to goals that the patient values. In my clinical experience, this tends to occur when goal attainment directly affects length of stay.

As the earlier autoethnographic study by Bright and colleagues revealed, external pressures and the 'tick-box' mentality can lead to compromised, and potentially ineffective, practice (Bright et al., 2012). The upcoming analysis of qualitative studies about goal setting will expand upon this idea (Section 2.3.3, page 63). Working towards highly-valued goals may place demands on time and resource that are considered by professionals to be too difficult to accommodate within a clinical setting, especially when one's priority may be to discharge patients as soon as possible. In these situations, the patient's personal rehabilitation goals might be amended to goals at the level of activity/impairment, under the guise of being 'more realistic' to achieve.

Furthermore, for an individual with disability, it is not uncommon to have goals that are implicit. The desire to achieve a certain future state is, to a degree, always present in ordinary, human consciousness. This desire may be augmented, or felt more keenly, after a sudden change in health state, such as having a stroke. Goals to get better are likely to

be deeply personal, related to the person's way of making sense of what happened, and how they should think about the future. Therefore, persons with stroke may not always feel like iterating these goals to others.

It is clear that an exploration of goal setting in stroke would not be complete without contemplating how the people directly involved in the process feel about it – on both sides. The following section will describe two qualitative studies: firstly, one that explores the views of physiotherapists, followed by one that explores the goal setting experience of people with stroke. Finally, because the concept of person-centredness has been highlighted in the conclusion of other goal setting studies, a systematic review and synthesis will delve deeper into the barriers preventing person-centredness in stroke.

2.3.3   Qualitative studies in goal setting

In the previous section, we established that quantitative evidence was lacking for goal setting improving outcomes at the activity and participation levels for people after stroke. There was, however, a small improvement in health-related quality of life. Multiple studies have explored different types of goal setting, and how it should best be done, but little overall has changed in the way goal setting is employed in rehabilitation in daily practice. Qualitative research allows one to delve deeper and examine the elements that contribute to professional apathy.

Lloyd and colleagues sought to explore physiotherapists' perceptions of their experiences with goal setting in the sub-acute stages of stroke in hospital (Lloyd, Roberts, & Freeman, 2014). The investigators interviewed nine physiotherapists with varied levels of experience. Grounded theory was used to elicit common themes.

First, the therapists described having to negotiate with patients who had higher expectations than their own. It was the physiotherapists' view that these expectations led the patients to desire to set goals which therapists deemed as 'less realistic'. The discrepancy in expectations meant that the two parties had to meet somewhere in the middle, i.e. negotiate.

Second, the physiotherapists also described a sense of having to act as a mediator by making the goal for the patient then presenting this to the multi-disciplinary team (MDT) in language that was 'acceptable to the team'. This was followed by the need to negotiate the appropriateness of the goal in the patient's absence.

While the physiotherapists were trained in goal setting, they felt that experiential, informal learning with senior staff was most effective for developing their skillset. How they felt about the role of goal setting in stroke rehabilitation also evolved with experience. Novice physiotherapists held an initial mechanistic view, valuing structure and technicalities of the process, while physiotherapists with more years of experience felt that their earlier work 'missed the point' (Lloyd et al., 2014). With experience, they believe they have learned to focus more on empowering patients to 'have a say'.

Lastly, it was also apparent that as part of the workplace culture and expectations, physiotherapists felt pressured to constantly balance the opinions of consultant rehabilitation physicians who thought of goals as 'practical rehabilitation tasks'. In contrast, therapists believe theirs is a 'theoretical, highly-evolved type of goal setting' (Lloyd et al., 2014). This paper does not provide definitions or elaborate on this statement in further detail. The following diagram was included to illustrate the various components that the physiotherapists had to take into account.

The language used in this study clearly described physiotherapists taking a more active role in the goal setting process, by their 'making' the goal, and 'negotiating' with the team and the patient. Figure 4 is taken from this paper, depicting the authors' impression of the continuum of goal setting from patient-directed at one end to therapist-directed goal setting at the other. This language seems appropriate only when working with the group of patients who may prefer to take a more passive approach.

Figure 4. Schematic representation of collaborative goal setting, along a continuum from patient-directed to therapist-directed.
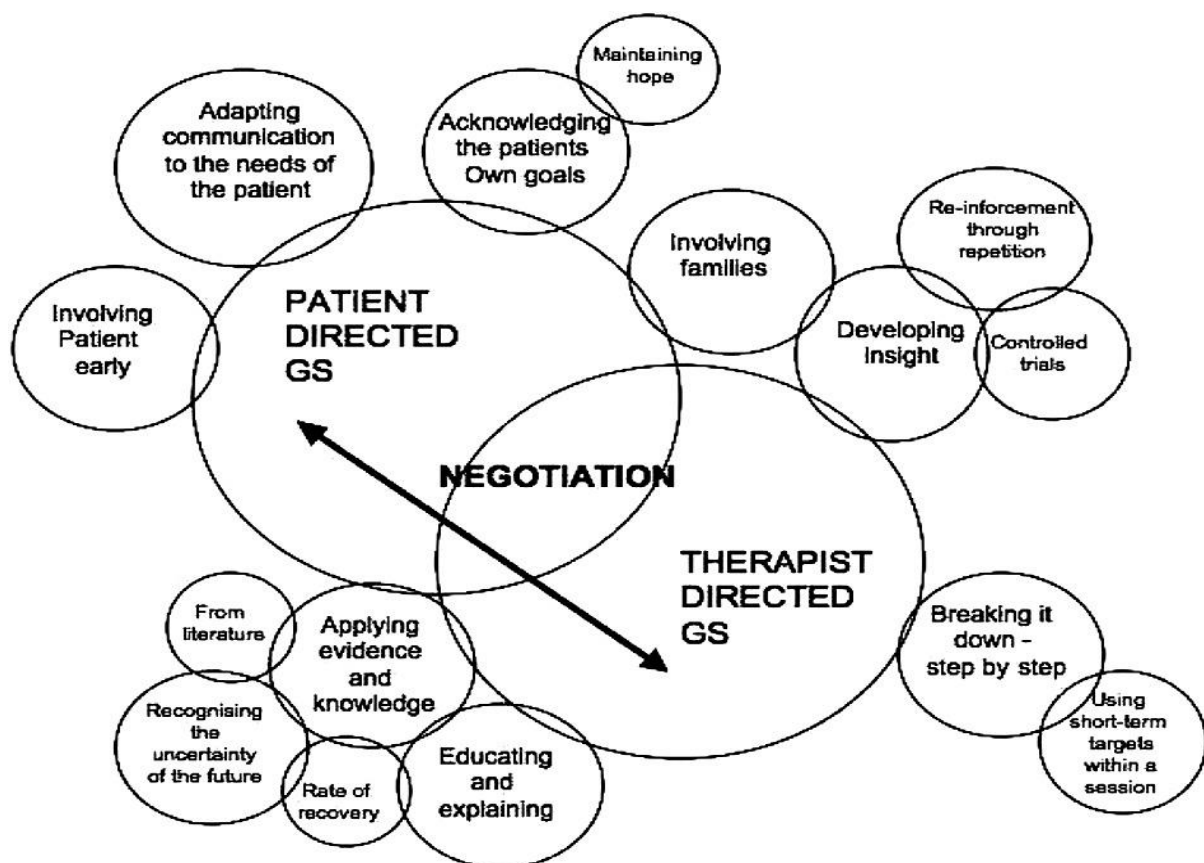
But who might these people be, those who prefer to be passive with decision-making? Psychologist Auerbach's research discovered that while the vast majority of people desire informational control, the desire for decisional control is reduced particularly in those who are older, have more severe disease and are less educated (Auerbach, 2001). These conclusions may still hold today despite the influences of widespread social change. These patients may consider therapists to be the experts and themselves the novices, who are to follow a set plan already made up for them. What the patients may not realise is that shifting the responsibility for setting goals to clinicians can increase the chances that their goals are set at the ICF level of impairment or body function. Working towards these goals may involve repeating mediocre exercises or tasks, which may hold little value or meaning for the patient.

While passive individuals may not wish to direct their goal setting, this is no reason for their rehabilitation not to be patient-centred, if collaboration between therapist and patient remained a priority. Auerbach also established that how much decisional and behavioural control one sought was found to be strongly influenced by whether one thought their involvement would positively influence the outcome of their situation (Auerbach, 2001). Patients may desire to be more involved if they are supported to feel like their opinions mattered. Similarly, Ozer and Kroll explained that patients are motivated to participate actively in rehabilitation if they perceive themselves as likely successful agents of change (Ozer & Kroll, 2002).

Patients' perceptions of goal setting

In a New Zealand-based qualitative study, patients expressed many diverse ideas about goals that differed from the narrative conventionally used by therapists (Brown et al., 2014). The purpose of Brown's study was to explore patient experiences of goal setting in stroke rehabilitation to better understand how to apply goal setting in practice.

This study was conducted out of four rehabilitation units in New Zealand and was nested within a pilot clinical trial (N = 41) which randomised participants to either 'usual team approach' or an 'additional structured goal setting approach' using the Canadian Occupational Performance Measure (COPM) (Law et al., 1990). The qualitative study involved ten participants: four from the intervention group and six from the control group. Participants who had cognitive impairment (Mini-Mental Status Examination [MMSE] < 24), aphasia, significant visual or auditory impairment or who were non-English speakers were excluded. Participants were interviewed in their homes 12 weeks after discharge from hospital and were asked about their experiences and perspectives of goal setting during inpatient rehabilitation and the early days of returning to the community.

The major finding from this study was that patients had diverse ideas about goals that differ significantly from therapists' views. Patients tended not to have specific goals during inpatient rehabilitation other than **continual improvement.** Their main focus was on the idea that they would 'keep getting better'. They emphasised looking ahead and noting day-to-day progress.

The types of goals that patients preferred were:
- Small, short-term goals that allowed boosts of confidence once achieved, and
- Extremely ambitious goals that would maximise performance and maximum possible improvement.

The goals set by rehabilitation therapists were considered to be *'common sense'* goals that accommodated basic survival needs, like self-care and being able to walk. In patients' minds, these contrasted with the goals that patients desired the most, which aimed for their pre-stroke function and lifestyle. These were considered *'special goals'*, described as

"*being able to do what I've always done*". Patients felt it was their responsibility to fight for their lifestyle while not necessarily being assisted by therapists. Attainment of special goals was considered '*the icing on the cake*'.

Being told that one was not going to recover pre-stroke abilities fully made it difficult for patients to be specific when setting goals. This unpredictability about recovery led patients to feel reluctant about committing to one particular goal. However, some participants still aimed for ambitious goals, and kept these to themselves. A quote from a participant in this study follows:

Quote 1

'The physio said to me – look, we'll do the best we can but I don't want you to over-expectate (sic) because if you don't do it, I don't want you to come crashing down, you've got to realise that you might plateau off. So at the back of my mind I always thought yep I can see that, but I'm going to bloody well walk before Christmas. I just didn't share it with anyone. I just told myself." (Brown et al., 2014)

Recovery was, however, seen as a natural process. Sometimes, participants felt that setting timeframes could be detrimental and demoralising if the goal was not met.

The authors of this qualitative study stated that there was little empirical evidence about the effect of involving patients in goal setting on overall health outcomes. They argued that this made it difficult for teams to decide on the best approach. This seemed like an unusual conclusion after such an insightful paper on how patients viewed goal setting. It would seem unwise and irresponsible to exclude patients from the process in the first instance, and only include them once there was adequate 'evidence' to show benefit of their involvement. Ultimately, the goals belong to the patients. I think that they should be the ones who own them, and the process of coming up with them.

Systematic review and meta-synthesis of person-centredness in goal setting

The significance of patient-centredness in goal setting has been appreciated in other research. Rosewilliam and colleagues conducted a systematic review and meta-synthesis of patient-centred goal setting in stroke rehabilitation. To ensure that data were comprehensive, quantitative and qualitative studies were included. This review sought to 'explore and map out from the literature the nature and extent of application of the patient-centred goal setting concept in current stroke rehabilitation practice' (Rosewilliam, Roskell, & Pandyan, 2011).

18 qualitative studies, eight quantitative and one mixed methods study were included in the analysis. These studies satisfied the criteria of using a patient-centred concept to study the goal setting process, fully peer-reviewed and published in English. The findings from the qualitative studies were extracted, summarised into one document then open coded. Overarching analytical themes were derived based on similarities in codes.

The quantitative research findings could not be meta-analysed as only one of the eight quantitative studies analysed was a randomised controlled trial; the others were cross-sectional surveys, retrospective analyses or case series. The total number of patients with stroke in these studies was 467, although one study did not define how many of its patients had stroke. The subject matter of the findings of the quantitative studies was examined and placed under the qualitative themes. The review found that **patient-centred goal setting was surprisingly uncommon**, despite recommendations that it be standard practice.

The following themes were presented. The first theme was that of **patients' perceptions** of patient-centredness in goal setting. Patients considered goal setting to be important and expected that rehabilitation training would improve their life situation. Making

progress in meaningful goals had been good for their self-image and had been helpful as a coping mechanism. However, patients perceived that they did not control the goals and their involvement in goal setting was passive. They put this passivity down to reasons such as their being too ill to participate, their feeling of unpreparedness to participate due to lack of knowledge and information about their condition, and difficulty accepting the stroke had occurred, especially in the early stages. Patients were critical of health professionals and the health system of being prescriptive and inflexible about goal setting as an intervention.

The second theme discussed **professionals' perceptions** and identified a perceptual practice gap. Professionals largely believed that their practice was patient-centred, and therapists believed that the activity-limitation goals they had set *for* patients were in line with the patients' functional goals. This wording is notable for the fact that therapists admitted that setting the goals had been their responsibility.

However, when shown evidence that the patients' social and occupational needs had not been explicitly incorporated into treatment goals, therapists revealed their perceived barriers to fully adopting patient-centredness. These reasons included: feeling that the patient was incapable of actively engaging in the process due to lack of knowledge or expertise, the patient's lack of confidence, the patient having unrealistic expectations about future goals and their lack of cooperation, therapists' concerns about future risks to the patient, sociocultural barriers, and environmental and resource limitations. The tone used here, at least for the patient-related barriers, is paternalistic.

The third theme described the **actual** status of patient-centredness in the practice of goal setting. Different 'types' of goal setting were identified from the studies, including: problem-oriented, needs-based, impairment-based, patient-centred, therapist-controlled, and therapist-led. Evidence from qualitative and quantitative studies showed

that fewer than 25% of the patient-participants actually took part in the goal setting process. Also, most patients were neither given verbal nor written information about goal setting, nor were they told when professionals were setting goals and planning individual treatments for them. In rehabilitation services, goal setting was mostly done by the multi-disciplinary team based on their assessments of the patient and the available resources. These goals were then usually conveyed to the patient and the family in a formal meeting.

The fourth theme examined the **consequences** of these discrepancies mentioned above. Clinicians viewed recovery from the point of the occurrence of stroke, while patients viewed it as achieving toward their pre-stroke status. This echoes the *'special goals'* as described earlier in Brown's paper (Brown et al., 2014). Patients, therefore, chose goals that improved their level of participation, such as mobility and social integration, in order to recapture their pre-stroke lives. Most of the professionals' goals for the patient were set at the level of impairment and activity. This dichotomy led to conflicts not only in the goal setting process but also affected other aspects of the therapeutic relationship, such as communication and trust.

The authors also showed that the health system contributed to barriers to patient-centredness, for example, by being too rigid with requiring formal assessments to be completed. Limited contact time also impeded the therapeutic relationship.

This systematic meta-review by Rosewilliam and colleagues revealed insights into a system in which people who worked believed they were doing the most good, despite evidence to the contrary. The examination was thorough. Unfortunately the perceptual-practice gap, and the barriers and attitudes within stroke rehabilitation and goal setting remain largely unchanged today. Being person-centred appears to be hindered by opposing perceptions, attitudes, and lack of time and resource.

As a conclusion, the authors recommended that education be provided to train professionals to develop qualities of empathy, respect for patients' wishes, and to prevent feelings of professional threat during the process of empowering patients. It was suggested that this education and training could be incorporated within in-service training or as continuing professional development programmes.

There were two major flaws to this conclusion. First, it presumed that such training was neither delivered nor received during the therapists' initial training. It also presumed that empathy had to be 'taught'. That is a bold presumption to make, since most people who pursue professions in healthcare tend to be people who 'care'. Second, 'more education' does not address the system in which therapists are forced to work – a system that is driven by external pressures, limited funding, time and resources, and paperwork and targets which are enforced (Bright et al., 2012). It is plausible that a reductionist mentality develops out of necessity, not because health professionals prefer checklists. An improvement in attitude, empathy, and satisfaction with the goal setting process will only come if those who control the requirements of the system recognise the importance of putting the patients' needs first, and choose to design the rehabilitation service around those needs.

As the content and delivery of outpatient rehabilitation by therapists have been explored, the intervention of a different support role will now be examined. It may be possible that delegating the role of patient advocate to another trained member of the multidisciplinary team might improve patient outcomes. When first introduced, stroke liaison workers were thought to be helpful in supporting patients with stroke and their families through their journey. The evidence for the role of a stroke liaison worker will be discussed in the following section.

2.3.4   Stroke Liaison Worker

The role of the stroke liaison worker/family support organiser was first introduced by stroke associations to support a stroke survivor's recovery. This person could come from a social work or health background or be a voluntary layperson trained in the role. It was thought that having a person who was able to follow the stroke survivor from hospital through to their life in the community would ensure the former could educate, provide information and social support, and liaise with health services. The stroke liaison worker was expected to help the patient cope with the provision of a large amount of information associated with stroke: secondary prevention, investigations, rules around driving, and instructions from therapists. This role was intended to help to mitigate the sudden upheaval of stroke by reiterating information.

Of note, it is important to review the stroke liaison worker literature to explore whether the positive outcomes from the MaPSS trial could be related to a similar role played by the research assistant who delivered the Take Charge session. It is possible that readers may interpret the results of MaPSS as being due to social support, advice, and liaison received by the person with stroke.

Mant and colleagues tested the role of the stroke liaison worker in a randomised controlled trial of 323 patients and 267 carers, and found no significant effects on patients. However, carers seemed to benefit from the presence of a stroke liaison worker. Carers in the stroke liaison group had significantly increased social activities and quality of life by six months compared to those in the control group (Mant, Carter, Wade, & Winner, 2000).

Furthermore, in a subsequent systematic review, Ellis and colleagues found evidence supporting the role to be less convincing. The Cochrane review included 16 RCTs (14 published and two unpublished) of a stroke liaison worker compared with usual care

(Ellis, Mant, Langhorne, Dennis, & Winner, 2010). Data were provided for 4759 urban patients from four countries: Australia, the Netherlands, the United Kingdom, and the United States. The authors excluded stroke liaison workers that appeared to have only a single facet to their role, for example, if their role was solely to liaise with other healthcare providers.

Three broad categories of stroke liaison worker were tested in the treatment arms:

Proactive and structured	Contacted all people with stroke, arranged a fixed number of visits, and provided a protocol-based programme not tailored to the person.
Proactive and tailored	As above, but topics discussed at visits were specific to the needs of the person, such as mental health and risk factor control.
Reactive and flexible	Intervention to meet needs as they arose or as requested by patients, with an open period of follow-up and a variable number of visits.

The control groups received usual care.

The primary outcomes were subjective health status (as measured by the GHQ-12, SF-36, or EuroQOL) and extended activities of daily living (as measured by the NEADL or FAI). The analysis did not show a significant difference for either of the two primary outcomes. The standardised mean difference (SMD) for subjective health status was 0.03 (95% CI -0.11 to 0.04, p = 0.34). The SMD for extended ADL was 0.04 (95% CI -0.03 to 0.11, p = 0.22).

However, a pre-defined subgroup analysis was undertaken for BI categorised to mild, moderate, and severe dependency. Those with baseline BI 15-19 (mild dependency) showed a significant reduction in dependence (OR 0.62, 95% CI 0.44 to 0.87, $p = 0.006$) for those who were supported by the stroke liaison worker. Including death in the analysis (death or dependency, mRS > 2) showed similar results for the subgroup (OR 0.55, 95% CI 0.38 to 0.81, $p = 0.002$). This risk difference equates to 11 fewer dependent patients for every 100 patients with mild dependency seen by the stroke liaison worker. It is important to recognise that because this was a subgroup analysis, the results need to be interpreted with a degree of caution.

The reasons for this result are unclear, but some do come to mind. In a clinical setting, patients with mild stroke severity tend to be discharged earlier than those with moderate to severe severity (BI < 15). Those discharged early may miss out on access to information in the form of ongoing interactions with the health service. Stroke severity is also one of the major determinants of outcome, and individuals with moderate to severe stroke may not be able to achieve a reduction in dependence with the stroke liaison intervention alone. Conversely, those who are independent (BI 20) may derive less benefit from information provision as there is little room to improve and may not need the social support or liaison with other health services.

It is, therefore, possible that patients with mild dependence (BI 15-19) are more responsive to an intervention like the stroke liaison worker. Of interest, the research assistants who undertook the Take Charge session in the MaPSS trial shared similarities with the description of the 'proactive and tailored' stroke liaison worker. The mean BI score of the study population in MaPSS was 16.7, and the Take Charge session significantly reduced dependence and improved health-related quality of life (M. Harwood et al., 2012) (Section 2.5 page 100).

The use of the stroke liaison worker has since largely fallen out of fashion, and in most New Zealand centres, the role no longer exists. This is regrettable, as the Cochrane review showed that patients appeared more satisfied that someone had listened to them, and carers appeared to be more satisfied with aspects of care provided. Possibly, combining the results with patients with all levels of stroke severity might have diluted the effect of the stroke liaison worker in patients with mild dependence, or that particular result had been due to chance. It is also possible that the 'proactive and tailored' approach might have been more effective than other approaches, but this is difficult to prove because of the heterogeneity of the interventions when combined.

In conclusion, there was no convincing evidence that a stroke liaison worker improved important outcomes for people with stroke. These findings highlight a need to continue to seek an intervention that benefits people with milder stroke severity living in the community (BI 15-19) because this subgroup may be more sensitive to intervention. Furthermore, such an intervention might look similar to a stroke liaison worker: a person who forms a connection with the patient and offers a personalised approach to care.

2.3.5   Caregiver-led rehabilitation

The following study was completed after the research component of this thesis began. The study results were published while TaCAS was actively recruiting participants. After some consideration it was included in the literature review because of its relevance as a novel approach to community-based rehabilitation in stroke, and because its results further question the effectiveness of therapy-based rehabilitation, as explored in an earlier section (Section 2.3.1, page 44).

To overcome the barriers of lack of time and limited resources of therapists in the outpatient setting, a group of researchers hypothesised that a novel approach to

delivering therapy to patients with stroke in the community of a low to middle-income country (LMIC) might increase therapy's effectiveness (Lindley et al., 2017). This study was set in India, where the health system did not provide inpatient rehabilitation after stroke, and most patients were discharged to rural communities with little to no follow-up.

The investigators wondered whether a caregiver could provide therapy at home. What if a caregiver or next-of-kin was taught by a therapist as much as they could about what the therapist knew, for example, specific exercises, strengthening, balance, goal setting, fatigue management, and on discharge the caregiver was responsible for delivering this therapy to the patient? A caregiver who lived with the patient would be able to apply the knowledge more frequently and with greater flexibility, perhaps even increasing the patient's exposure to therapy time compared to what they would get if they were able to access an outpatient therapist. Caregiver-led therapy seemed to be one of the few methods available to deliver therapy-based rehabilitation to people with stroke in India.

A collaborative group between India and Australia tested caregiver-led rehabilitation after stroke in 1250 patients in India, in the Family-Led Rehabilitation After Stroke (ATTEND) randomised controlled trial (Lindley et al., 2017). This intervention was hypothesised to increase survival and independence after stroke unit admission and began with the training of a caregiver to undertake rehabilitation for the patient during the admission. Continuation of training by the local trial coordinator (a rehabilitation professional, usually a physiotherapist) took place at up to six home visits. An intervention manual for the coordinators and family members ensured the training covered comprehensive disability and impairment assessment, information provision, joint goal-setting, limb positioning, and encouragement of the practice of task-based activities. Participants were randomly assigned to the intervention or to usual care, which involved inpatient assessment and rehabilitation by a physiotherapist, with post-

discharge care varying from none to some outpatient therapy sessions. Outcomes were assessed at three and six months. The primary outcome was death or dependency at six months.

The methodology was rigorous, and the study was well-powered (Alim et al., 2016). Caregivers were trained for three hours in hospital and a further three hours at home. Furthermore, log books suggested that intervention subjects received on average 17.8 hours of caregiver-led rehabilitation in the first 30 days after discharge. 97% of participants were followed-up at six months, and outcomes assessors were masked to allocation.

The ATTEND trial confirmed that caregiver-led rehabilitation was an ineffective addition to status quo practice (Lindley et al., 2017). Training caregivers to rehabilitate people with stroke made no difference to death or dependency at six months. This result was disappointing, as one may have supposed that caregivers might have made the rehabilitation experience more person-centred, and were not under the same systemic pressures of the health system as hospital therapists. However, while this study convincingly showed that the training of caregivers was not a solution to India's lack of comprehensive outpatient stroke care, it also gave rise to questions about why the method did not work in the regions studied (which were located within 50km of a hospital).

First, it is possible that activity went unmeasured. As the activity log book was only used in the intervention subjects, it is unknown how much control subjects completed actual activity or 'made-up' rehabilitation in the first 30 days after discharge. The pilot trial also showed evidence of contamination between groups as the rehabilitation manual given to intervention participants aroused the interest of other patients (Pandian et al., 2015). It is also possible that what the control subjects did end up doing was just similar to, or as

good as, the tasks prescribed by Western rehabilitation. This might be an indication of the principle that for goal setting to work, it may not need to be enforced as an iterated or formalised process. Perhaps this was a real-life example of the internal goal setting phenomenon, described earlier in qualitative studies (see Quote 1, page 68). It seems plausible that the simple desire of a person that they be able to do something might be an evolutionary instinct necessary for survival, and does not need to be shared, spoken, or written down.

Human nature is the other force that cannot be controlled. It is inherently difficult for human beings to sustain initial motivation. Even in the ideal scenario that all concepts were fully understood and retained by caregivers <u>and</u> all caregivers employed every bit of the rigorous training they received in 6 hours to their home-based rehabilitation, when left to their own devices I believe people (caregivers and people with stroke) would have mostly likely 'done their own thing'.

Perhaps this idea is key to understanding the ideal self-management intervention. I believe it does not matter who prescribes activities for people with stroke, whether it comes from therapists or carers. People will only meaningfully and consistently do what comes from within themselves.

Methods aside, there may be other reasons why caregiver-led rehabilitation was ineffective. Earlier chapters of this thesis explored the lack of evidence supporting therapy-led rehabilitation in reducing death and dependency. ATTEND confirmed this further, as subjects showed no difference in death, disability, participation, or quality of life despite receiving significantly more hours of home-based rehabilitation than those in the control group. If the therapy itself is not sufficient when delivered by professionals, it is not surprising that therapists teaching lay caregivers to employ the same therapy is ineffective.

A further critique would question the effectiveness of the training and how much information was retained and then delivered by carers, although measuring this would have been difficult and unrealistic. As there were a large number of therapist-trainers in this study, training logs were completed and fidelity was guided by site visits and physiotherapist contracted to help with training (Alim et al., 2016). It is, however, unclear how one would know whether the carers had acquired the skills to continue prescribing activities that would remain challenging to subjects.

Lastly, the difference in outcomes between male and female subjects may also reflect entrenched beliefs about gender roles in the family. In the pre-specified subgroup analysis of sex, men had reduced odds of death or dependency at six months compared to women. While it may be a somewhat old-fashioned notion in today's Western society, in the study population it may have been more common for women (usually spouses or daughters) to actively support men following stroke, rather than vice versa. Male carers may have continued working and might have been less inclined to motivate their spouse to engage in rehabilitation, compared to female carers. It is also possible that the male carer might also have done more for the person with stroke, rather than encouraging them to perform tasks for themselves.

While the negative trial results for a novel intervention were disappointing, the information gained from the trial was valuable. In thinking about designing a new intervention, it might be important to think about how to maintain consistency if information is delivered in sessions, and how to reduce or minimise gender bias. The ideal intervention might focus on empowering the person with stroke to think of ways that they could help themselves and possibly encouraging them to delegate tasks or roles to their carers.

Society has designed and funded outpatient rehabilitation services for patients with stroke in the face of limited evidence for the effectiveness of current interventions. Traditional, therapy-led rehabilitation may reduce the risk of dropping one point on the Barthel Index for every 13 people who receive it. This benefit is unlikely to be clinically meaningful. Goal setting in rehabilitation is not done in a person-centred way, and may at best marginally improve self-efficacy and quality of life. Large, robust, randomised controlled trials of goal setting in persons with stroke do not exist, yet goal setting is now part of a contractual requirement in rehabilitation service delivery. These components still mostly form the basis of current stroke rehabilitation in the community. Lastly, training another individual to be a liaison between the patient and the health system, and transferring the knowledge and skills of therapy to a caregiver have been shown to be ineffective. The optimisation of 'others' does not seem to benefit the person with stroke.

So, the question must be asked. What about the person with stroke, themselves?

One approach that has been proposed, not only in stroke but also in the management of other chronic conditions, has been self-management. The following section will explain the basis of self-management in health, and explore the evidence for self-management techniques tested in stroke.

2.4   Self-management

In the previous section, evidence for interventions used in routine outpatient rehabilitation of people with stroke were detailed. Therapy-led rehabilitation possibly results in a small degree of effect at the level of activity limitation, for every 10-13 people with stroke who receives it. There is very low quality evidence that structured goal setting may improve self-efficacy, but qualitative research shows that patients are rarely directly in charge of setting those goals, and their social and occupational needs are not met. It is possible that the action of setting goals may cause more strain on the therapeutic relationship between therapist and patient while in the pursuit of better outcomes. Even the novel approach of family-led rehabilitation after discharge had no effect on quality of life dimensions, participation restriction, death, dependency, or institutionalisation.

Perhaps it is timely to wonder whether we are approaching the recovery of a person with stroke correctly. Instead of doing things *to* the person with stroke, what if clinicians were able to support or facilitate the person with stroke to do things *for themselves?* Would it be possible to empower the person with stroke to manage their recovery?

Maximising a person's own ability to manage their health is the cornerstone of self-management therapies. This chapter will touch briefly on the history of self-management as a concept, and describe several studies in wider health conditions, then more specifically in stroke. These studies have contributed to evidence supporting self-management strategies today.

In the 1950s, social psychologists developed the Health Belief Model to help explain and predict health behaviours especially in relation to engagement with health services and

poor uptake of screening for tuberculosis (Rosenstock, 1974). A person's perception of benefits, barriers, seriousness of their illness, their susceptibility to the illness, and specific cues to action were thought to be factors that contributed to how likely a person would be to engage in health-promoting behaviour. Much later in the 1980s, self-efficacy was added to the existing model.

Self-efficacy was described by Bandura as 'the belief in one's capabilities to organise and execute the courses of actions required to produce given attainments' (Bandura, 1997). Simply put, it is a person's own beliefs of how well they can cope and act. Early self-management interventions were designed with a view to increasing self-efficacy.

Self-management began as a broad concept of managing health conditions in the 1970s, when it became apparent that chronic disease rates were rising. One of the first places the term was used was in the field of rehabilitation in children affected by chronic asthma (Creer & Burns, 1979). In high-income countries, population growth and a rise in life expectancy contributed to a high prevalence of heart disease, lung disease, arthritis, and diabetes mellitus. These conditions required those afflicted by them to actively engage in regular visits to health professionals, self-monitoring of symptoms and adherence to medications. Those who failed to do so had higher morbidity and mortality, more frequent presentations to hospital and longer lengths of stay. From a government perspective, this phenomenon led directly to higher health budget expenditure.

Budget-conscious governments and public health-conscious physicians began to invest in real-life studies of behavioural change, putting the theories developed by social psychologists into practice. For example, the National Health Service of the United Kingdom embraced the idea and implemented it in patient management to try to reduce costs. Subsequent evaluations suggested that their interventions did not improve outcomes, costs or readmissions as planned. The difference between expectation and

reality probably lay in *how* one goes about training people to self-manage, and reaching a consensus has been hampered by heterogeneity of the various interventions tested. For example, would one-on-one sessions be more effective than sessions taught in groups? Would task-oriented content produce a different effect to inspirational anecdotes? How would teaching or training a person translate into meaningful ownership of their condition, and subsequent self-management actions?

2.4.1 The Chronic Disease Self-Management Project (CDSMP)

The first seminal study that provided evidence for a self-management's effectiveness was published by Lorig and colleagues in 1999. The content of the Chronic Disease Self-Management Programme (CDSMP – also known as the Stanford Self-Management Programme) was based on the generic Arthritis Self-Management Programme, and developed from information obtained through a literature review of existing patient education programmes, and qualitative data from patient focus groups (K R Lorig et al., 1999).

1140 participants in California, the United States, were randomised either to receive the CDSMP or control for six months. Participants were recruited using public service announcements and referrals from health organisations, and had to have a confirmed diagnosis of chronic lung disease, heart disease, stroke or chronic arthritis. The investigators excluded those who were younger than 40 years of age, or who had compromised mentation, or who had cancer treated with chemotherapy or radiotherapy in the previous year. Each CDSMP was led by a pair of trained lay volunteers who also lived with a chronic illness (the rationale being that they would be seen as positive role models), and was taught in seven weekly 2.5-hour sessions. Those in the control group did not receive any sessions but were offered the CDSMP at the end of six months. A total of 87 different volunteers delivered the CDSMP at some point in the study.

A number of different outcomes were measured. These were a combination of health behaviours, health status and health service utilisation at six months, determined by the completion of self-administered, mailed questionnaires. The National Health Interview Survey and a modified version of the Health Assessment Questionnaire disability scale were included as instruments.

83% of participants completed the six-month study, and subjects allocated to the CDSMP attended an average of five of the seven sessions. At six months, the treatment group demonstrated significant improvement in all four health behaviour variables ($p < 0.01$; number of minutes per week of stretching/strengthening and aerobic exercise, increased practice of cognitive symptom management, and improved communication with physician), and five of the health status variables ($p < 0.02$; self-rated health, disability, social/role activities limitation, energy/fatigue, and health distress.)

While results were positive for the self-management intervention, there were several limitations. First, for an initial randomized controlled trial testing self-management education it was unusual that people under the age of 40 were excluded. The investigators did not provide a reason for the exclusion but a possible contributing factor could have been that chronic illness was less common in younger people in the mid-1990s.

However, the exclusion does raise the question of whether the investigators believed that younger individuals were considered to be more intrinsically motivated or better at coping than older people. Should this matter if the definition of the condition was a chronic illness? If diagnosed with a chronic illness at a younger age, the young person would have to live longer with their condition and disability or adverse outcomes compared to an older person who, for example, might be diagnosed with congestive heart failure at 80 years of age. The burden of DALYs would be greater in a young person

with chronic illness. Therefore, it would seem that self-management would be equally relevant, if not more, to young people with chronic illness.

Second, it is difficult to determine the quality and consistency of the intervention because the sessions were conducted by so many different facilitators. The investigators did provide a guidebook which benchmarked the content of the sessions, despite it being delivered by multiple, trained, lay individuals. The book was based on content derived from focus groups and a literature review, but it is unclear whether the content might have been too general for different people with specific conditions. The content was taught over seven sessions in groups of about 15 people with different chronic conditions. On average, participants allocated to receive the CDSMP attended about five sessions each. Furthermore, trainers only held an average of two sessions each, which would lead one to question their familiarity and experience with the content and delivery of such a small number of sessions.

As the control group did not receive sham sessions, it is also impossible to determine whether the effects seen in the intervention group are due to the content of the sessions, or simply due to having attended sessions. The CDSMP sessions were also not related to the timing of diagnosis, so it is likely that those who had lived with a chronic illness for a longer period would have already developed coping mechanisms and the ability to live with their illness.

Finally, it is difficult to generalise these results to all persons with stroke. Only a small number of people with stroke were included in this study, and those with cognitive impairment were excluded. Therefore, it is difficult to say whether the CDSMP would be an effective tool for people with stroke until it was tested in a larger population of people with stroke.

Lorig and Holman went on to describe the five core skills of self-management in an article reviewing the history, definition, outcomes, and mechanisms of self-management (Kate R Lorig & Holman, 2003). The first skill was problem-solving, to ensure that difficult situations could be addressed and overcome. Second, having sound knowledge and information about health, symptoms and treatment was thought to be essential for people to make decisions. Third, self-management required the ability to locate and make use of appropriate resources, including support. Fourth, self-management required people to form a patient-provider partnership with healthcare providers. Finally, self-management involved taking action to change behaviour and master new skills.

Although they had not been fully described, these five core skills were reflected in the course content under the premises of coping, action planning and goal-setting. Those skills were thought to contribute to participants' confidence in managing their health and the perception that they could control their environment (i.e. self-efficacy).

2.4.2 Long term outcomes of the CDSMP

Lorig and colleagues continued gathering data for a further 4.5 years from the date that the initial cohort commenced the CDSMP (K R Lorig et al., 2001). After six months, those in the control groups were offered the opportunity to receive the CDSMP, and 72% of these waitlisted cohorts took up the offer. Data were gathered in questionnaire format at the following times: immediately before receiving the CDSMP, at six months, and at one and two years. Subsequently, all participants who had received at least one session (mean attendance 5.7 of seven sessions), and who had completed the outcomes questionnaire at one year were included in a longitudinal analysis. A total of 831 participants were included in the analysis.

The investigators used t tests to compare the baseline and one-year results of all the participants to determine whether the effects of the CDSMP persisted over time.

Between baseline and at one year there was no difference in self-rated health status, energy/fatigue levels, and social/activity limitations. An increase in disability was observed one year after receiving the CDSMP (0.081 at baseline to 0.845 at one year, $p = 0.025$). However, there were significantly fewer attendances to the doctor and emergency department, and participants reported a significant reduction in self-rated health distress (2.06 at baseline to 1.85 at one year, $p = 0.0001$) and an increase in their self-efficacy (6.03 at baseline to 6.32 at 1 year, $p = 0.0001$).

Some of the initial benefits observed at six months after completion of the CDSMP (including an improvement in the health variables of self-rated health and disability) were not sustained out to one year.

It is possible that the earlier follow-up captured the ongoing benefits of increased health awareness and motivation gained from attending the CDSMP, but over time those effects diminished. However, the one-year results were not all negative. The fact that seven weeks of group sessions had managed to reduce health distress and maintain increased self-efficacy at one year for people with a chronic disease was notable. The reversal or halting of physiological disease processes would have been harder to maintain with self-management alone.

Despite an increase in disability scores there were fewer attendances to health services, This might have reflected a better capability to cope with physical illness, or it could have been due to false confidence and neglecting needed healthcare, which led to increased disability. There were elements of psychological benefits being maintained by this self-management intervention, and from a holistic perspective of health this result might be considered positive.

2.4.3   Testing the CDSMP in people with stroke in Australia

By the mid-2000s, the Australian health system had implemented the CDSMP in the treatment of multiple conditions, although its use in those affected by stroke was still minimal. To evaluate its use in stroke, Kendall and colleagues tested the effect of the CDSMP in a randomised controlled trial of people with stroke (Kendall et al., 2007). The hypothesis was that the CDSMP would promote psychosocial recovery pathways, and implementing it within the first few months after discharge would maximise its capacity to alter recovery.

One hundred persons with stroke from a single centre in Queensland consented to be randomised to either the CDSMP or usual care, determined by a two-dice roll. Age ranged from 25-82 years. Inclusion criteria included: (1) no prior self-reported history of stroke, dementia or psychiatric illness, (2) sufficient expressive / receptive English language skills to take part, as determined by the treating speech pathologist, (3) expectation of discharge to own or a family member's home, and (4) a family member or friend who was willing to participate in the study with them ["enabler"]. The enabler role was not mentioned in Lorig's original CDSMP study, but the lack of an enabler would mean that individuals who were isolated or lived alone with minimal social support would have been excluded.

58 participants were allocated to the intervention and 42 to control. Data were collected at three, six, nine, and 12 months post-stroke via telephone, and the 7-week stroke CDSMP course was delivered between three and six months post-stroke. The primary outcome measures were the physical, psychological and social outcomes measured by the Stroke Specific Quality of Life (SSQOL) scale (Williams, Weinberger, Harris, Clark, & Biller, 1999). The Self-Efficacy Scale, as designed by Lorig, was used to assess the various dimensions of self-efficacy (K. Lorig, Chastain, Ung, Shoor, & Holman, 1989). To determine the effect of variation in attendance at the sessions, attendance at four or

more sessions was considered full attendance, and fewer than four sessions was considered partial attendance.

Information about baseline stroke severity was not available to allow consideration of casemix. This is unfortunate, as the control group showed a consistently lower self-efficacy score than the intervention group, even at baseline. It is, therefore, difficult to attribute this difference between groups solely to the CDSMP.

Furthermore, the control group received usual care rather than sham sessions, and subgroup analysis showed there were no statistically significant differences in outcomes between those who had partially or fully attended the sessions. The total number of sessions attended did not matter. This finding lends further weight to the argument that the content of the sessions, or the method of delivery of this content, had very little impact on the people with stroke' self-efficacy or quality of life.

Changes in level of self-efficacy led to positive effects on the main SSQOL outcome variables such as language, mobility, and mood. However, self-efficacy scores in both groups showed no statistically significant differences over time. The intervention group's level of self-efficacy did not change after receiving the CDSMP.

For all components of the SSQOL, the intervention and control groups did not differ significantly at six, nine or 12 months post-stroke.

The authors argued that the intervention had a significant impact on functional activities such as self-care, work productivity, and activities of daily living at the six to nine month period after stroke and the effect disappeared at 12 months due to 'improvements in the control group'. At best, it appears that there was a trend toward a temporal difference between both groups however this was not statistically significant.

A question that is more difficult to answer would be how effective could one consider an intervention to be if those who did not receive it managed to get there in the end on their own by 12 months, albeit with lower self-efficacy scores at baseline?

Kendall and colleagues' study was also hindered by its small participant number, uneven allocation, self-selection bias, and high attrition rate (71% follow-up at 12 months). No mention was made of assessor blinding, the absence of which could lead to bias.

However, the key finding from this study was that the impact of the intervention occurred even after controlling for self-efficacy. Self-efficacy levels were not different between groups. The implication is that the presumed theoretical mechanism on which the CDSMP was based may not after all be the method by which it exerted its effects. The authors conceded that '*it is possible that merely being offered an intervention of this nature, being exposed to other participants, having access to an instructional manual or knowing that ongoing group support is available may be sufficient to encourage participants to adopt self-managing behaviours.*' One might argue that some of this speculation could have been avoided by using a sham session for the control group – a point that would be taken into account in the design of the Taking Charge After Stroke study.

A concurrent qualitative study explored participants' perceptions of the self-management programme tested by Kendall and colleagues (Catalano, Dickson, Kendall, Kuipers, & Posner, 2003). Participants described the key benefits of the programme as enhanced social contact, increased awareness and knowledge about stroke, motivation to pursue goals and activities, and a sense of achievement.

2.4.4   Systematic review of self-management interventions in people with stroke

Since the promising results of the CDSMP were published, a number of other studies testing self-management strategies in stroke have been completed. A systematic review

conducted by Lennon and colleagues in 2011 summarised these studies (Lennon, McKenna, & Jones, 2013).

This systematic review included the aforementioned randomised controlled trial by Kendall and colleagues, as well as the Māori and Pacific stroke study (MaPSS), which will be described in Section 2.5, page 100.

The aim of this review was to examine the evidence base underlying self-management programmes *specific to stroke survivors* (Lennon et al., 2013). Much of the existing evidence supported the use of such programmes in long-term, chronic diseases, such as arthritis. As per the original CDSMP study, people with stroke tended to make up only a small proportion of participants in studies that evaluated generic self-management programmes. Therefore, the effect of such programmes on the outcome for people with stroke was unclear.

15 studies were included in the review, nine of which were randomised controlled trials. Study method was not restricted. Five of the randomised controlled trials had over 100 participants and provided level I evidence using moderate to high quality methods. The studies were conducted in New Zealand, Australia, the United Kingdom, and the United States. The total number of participants was 1233, aged 18 years or over. Mean age of participants was 67 years. Individuals in all studies had been discharged from acute care into community living, but the average time post-stroke when participants received the self-management programme varied between 24 days to over 4 years. Studies that did not explicitly describe a self-management component of their intervention (e.g. solely education or solely motivational interviewing), and those which included participants with other chronic diseases, were excluded. Of the included studies, nine studies excluded people with stroke with cognitive problems, and five excluded people with stroke with communication problems.

A variety of multi-component interventions were tested. These included:

- post-discharge, stroke-specific care management programmes;
- using a workbook containing information to help with planning and problem solving, care plans, coping resources, goal setting, personal risk guide;
- skills training;
- exercise;
- home visits;
- monthly phone calls;
- an inspirational DVD about stroke and stroke recovery featuring ethnicity-specific families;
- the Take Charge session – which included a rehabilitation checklist by ethnicity-specific facilitators (see page 100 for more detail)

The authors noted that all interventions appeared to include 'some element of information provision, problem solving, and goal setting.' In eight studies, the intervention was delivered in group format, and in the remaining seven studies it was delivered on a one-to-on basis.

Comparison groups either received standard post-discharge care, some generic written information about stroke (in MaPSS), or a placebo telephone call. In the pilot studies, those in the control group were waitlisted to receive the intervention after the trial was complete.

The five larger RCTs assessed outcomes at 3 – 12 months post-stroke, while the four pilot studies had a shorter follow-up of between 1 – 6 months post-intervention.

Six of the nine randomised controlled trials found significant treatment effects in favour of the self-management intervention. Participants who received the intervention showed statistically significant improvement over the control in: observer assessed disability ($p =$ 0.019) and confidence in recovery ($p < 0.001$); the subscales of family roles ($p < 0.01$) and fine motor tasks ($p < 0.5$) of the Stroke-Specific Quality of Life measure; stroke knowledge ($p =0.0003$); the physical component summary (PCS of SF-36) of the 36-item Short Form questionnaire ($p =0.004$) and modified Rankin scale ($p =0.023$).

One pilot study found that their intervention group had significantly improved well-being in neuro-motor function, complications, quality of life, risk management, stroke knowledge and self-management compared to control (K. R. Allen et al., 2002). However, the subsequent RCT of the same intervention conducted by the same team showed that the only statistically significant finding that remained by six months was improved stroke knowledge (K. Allen et al., 2009). Another pilot study found improvement in measures of self-efficacy related to communicating with a doctor; and the stroke-specific quality of life subscales of family roles, social roles, and work (Damush et al., 2011).

There are problems with conducting a large systematic review of self-management interventions in stroke, while including multiple different types of studies as well as heterogeneous interventions. First, there were no clear distinctions about what defined a self-management intervention, or, as the authors put it, "*a gold standard to which a self-management intervention must aspire*". Second, it is also unknown how much the intervention might be affected by the person(s) delivering it and the method by which it was being delivered. With so many variables at play, it is difficult to draw conclusions from the systematic review that are certain and generalisable.

The authors of the systematic review also mentioned the difficulty of analysing multiple studies with different outcome measurements, and the lack of consensus of which

measures should be most appropriate for self-management interventions. At which ICF level must an intervention have exerted its effect in order for it to be considered effective (Figure 7, page 137)? Was it enough that self-management affected a person's psychology by improving self-efficacy, confidence, and knowledge? Or would the effect of a self-management intervention need to translate to behavioural change, or improvement in activity? Or higher still, would it need to affect the level of participation, social interaction, or quality of life? Should the intervention be judged alongside its acute stroke intervention counterparts, considered effective only if it could reduce dependence, institutionalisation, or death? The consideration of choosing outcome measures against the ICF framework will be discussed further in Section 3.6.1, page 136.

Clinicians have accepted interventions into routine clinical practice that lack evidence for effectiveness in improving most of these outcomes. Therapy-led rehabilitation, which is widely practised, has evidence for limited benefits at the level of activity limitation, while having no effect on mood, quality of life, or self-efficacy. Goal setting in stroke hardly has fewer good quality, large RCTs to support its use than self-management interventions and yet goal setting is embedded as a requirement for rehabilitation service delivery. Based on this systematic review, self-management programmes show comparatively more promise in improving outcomes for those living in the community after stroke.

In their discussion, Lennon and colleagues signalled that further high quality RCTs of self-management interventions are needed before they would recommend inclusion of self-management interventions into routine, clinical practice. They noted that a cost-effectiveness analysis would also provide much needed information to inform how best to implement such an intervention into clinical practice.

Not long after planning for the Taking Charge After Stroke (TaCAS) study began, the Cochrane Collaboration published an updated systematic review of self-management interventions in stroke, using quality of life as the primary outcome measure. While the latter was not only felt to be more appropriate than measures of impairment or disability, it was also reassuring that we had chosen to evaluate the effectiveness of the Take Charge session at the same level. The Cochrane results will be summarised in the following section.

2.4.5 Systematic review of stroke-specific self-management interventions

It is important to include the Cochrane systematic review in this literature review of self-management in stroke because unlike the previous systematic review by Lennon and colleagues, the Cochrane review included studies which tested generic self-management interventions, not only those that were stroke-specific. So long as the data for people with stroke were available to be analysed separately from participants with other conditions, these data were included in the analysis (Fryer, Luker, McDonnell, & Hillier, 2016).

This review comprised 14 RCTs conducted between 2000 and 2015, totalling 1863 participants from high-income countries, all aged 18 or over. Participants had to be living in the community and suffered stroke based on the WHO clinical definition, but the time from stroke to intervention was not restricted. Included RCTs had to test a complex intervention that focused on more than one deficit or risk, and which included at least one self-management component such as: problem solving, goal setting, decision making, self-monitoring, coping with the condition, or an alternative method designed to facilitate behaviour change and improvements in physical and psychological functioning. Interventions that solely provided education or exercise to participants were excluded. Control groups received either an inactive control intervention (i.e. usual

care, waiting list control), or an active control intervention (i.e. information only or alternative intervention not considered to be self-management).

As the Take Charge session fitted these criteria, the Māori and Pacific stroke study (MaPSS) was the only trial from New Zealand included in the analysis. The MaPSS study will be described in detail in Section 2.5. Previous systematic reviews by other groups had been broader in their inclusion criteria, for example, including studies if the term 'self-management' had been used to describe an intervention.

The primary outcome measure was quality of life: health-related, as measured by the 36-item Short Form version 2 (SF-36v2) or the EuroQol (EQ-5D); or general, as measured by the World Health Organisation Quality of Life (WHOQOL)-BREF. Secondary outcomes included self-efficacy, activity limitations, participation restrictions and impairments.

Quality of life scores were available for 469 participants from six trials (26% of total participants included in the review). Three trials used the SF-36 physical functioning and mental functioning scores, and three used the Stroke Specific Quality of Life scale. The pooled estimate of effect for all trials was a standardised mean difference (SMD) of 0.34 (95% CI 0.05 to 0.62, $p = 0.02$; moderate quality evidence) compared to control. Therefore, participants who received self-management interventions had significantly better quality of life than those who received usual care or an intervention with a small active component. Removal of the two trials with active controls (MaPSS included), strengthened the effect to an SMD of random effects of 0.44 (95% CI 0.05 to 0.82, $p = 0.03$).

Self-efficacy data were available for 403 participants from six trials (22% of all participants). Four trials used the Stroke Self-Efficacy Questionnaire (Jones, Partridge, & Reid, 2008), and analysis of pooled estimates gave a standardised mean difference of 0.33

(95% CI 0.04 – 0.61, p = 0.03) providing low quality evidence that those who received a self-management intervention had higher self-efficacy compared to those who did not. Data for activity limitation, measured by the Barthel Index in four trials, showed a trend toward significance in favour of the self-management intervention but this was not statistically significant.

The results of this systematic review suggest that ongoing study of self-management interventions in stroke may be the key to unravelling the 'black box' of rehabilitation. By improving health-related quality of life and self-efficacy, self-management interventions tailored to people with stroke showed promise in improving psychosocial well-being. Because the benefits were largely psychosocial, it would make sense to focus on ensuring that new self-management interventions are as person-centred as possible. Borrowing from goal setting terminology, for example, one would expect a self-management intervention not only to be person-centred, but *person-led*, as opposed to therapist-led. The more we pay quality attention to a person's needs, desires, hopes, fears, and dreams, the more we might be able to establish what is meaningful to the person and their recovery.

A novel, self-management approach was tested in a randomised controlled trial in Aotearoa New Zealand. This study was mentioned in earlier parts of this chapter as it had been included in several of the systematic reviews. For the first time in New Zealand, the Māori and Pacific stroke study (MaPSS) showed that an individualised, self-management intervention was effective at reducing dependency and improving physical health-related quality of life in Māori and Pacific people with stroke living in the community. The following section will describe MaPSS and its results, which influenced and shaped the TaCAS study of this thesis.

2.5 The Māori and Pacific Stroke Study (MaPSS)

In 2006, New Zealand researchers Harwood and colleagues embarked upon the Māori and Pacific Stroke Study (MaPSS). (M. Harwood et al., 2012) This section will describe the interventions tested in MaPSS, before describing the study itself.

2.5.1 Interventions tested in MaPSS: The Take Charge session and the DVD

The discrepancy in outcomes between Māori and European people with stroke has been well-described. A prospective study conducted out of three hospitals in Wellington, NZ, showed that Māori and Pacific people with stroke at 12 months had worse outcomes than their NZ European counterparts. (McNaughton et al., 2002)   Non-Europeans were more likely to be dependent (corrected OR 21.0, CI 3.1, 141), and have lower scores on the SF-36 PCS. This was despite non-Europeans being younger by about ten years at the time of stroke and having had better physical functioning immediately prior to the stroke. The OR was corrected for age and initial FIM score using multiple logistic regression. The OR is unusually large and imprecise because the study was small (Europeans n = 148, non-Europeans n = 33) and about a third of the non-Europeans were lost to follow-up.

Similarly, data obtained during 2002-2003 from the third Auckland Regional Community Stroke Study (ARCOS III) confirmed that this disparity was not unique to Wellington, but present in Auckland as well. (McNaughton et al., 2011) At six months after stroke, Asian and Pacific survivors had worse functional outcomes compared with NZ Europeans [Frenchay Activities Index, mean (SD): Asian 14.6 (10.7), Pacific 17.4 (12.4), NZ Europeans 21.3 (12.1)]. At the time, Pasifika made up a greater proportion of Auckland's residents (10.7% of total subjects) than anywhere else in the country, but a greater

proportion of Pacific people with stroke were dead or dependent at six months compared to all other ethnicities (Pacific 68.6%, European 59.5%, Asian 60.7%, Māori 57.0%).

Harwood studied the Māori perspective on rehabilitation and described a framework for improving rehabilitation services for Māori. (Harwood, 2010) This work suggested that interventions with particular foci would be most likely to make a difference to Māori outcomes.

These features included:
- good information for people with stroke and their families about what was possible following stroke,
- positive messages about life changes, and
- an opportunity for families to discuss the tensions between maximising recovery and 'looking after' a family member following stroke.

Interventions would need to be delivered through non-print medium, either face-to-face (*kanohi ki te kanohi)*, or in video format.

Two interventions were developed based on this information. First, a DVD recording of four Māori and Pacific people with stroke' stories, and interviews with their families, filmed professionally by 'Education Resources' (www.edresources.co.nz). In it, these 'role models' described how they were able to 'take charge' of stroke recovery. Major themes included risk factor management, information about resources and services, goal setting, and dealing with the ups and downs of rehabilitation. The overall message was a positive one for the individual and their family, which aimed to dispel some of the negative messages about stroke. The programme was approximately 80 minutes long (20 minutes for each story), and the DVD was left with a portable player and screen at the home for twelve weeks.

The second intervention was an assessment of rehabilitation and stroke prevention needs conducted by a trained, research assistant who understood some of the difficulties that exist for Māori and Pacific people with stroke. If required, the research assistant could also initiate referral to appropriate services. All major, identifiable needs were covered using a checklist. Following this, a goal setting component was undertaken. The research assistant elicited issues that would be specific and meaningful to the stroke survivor and their family. They were trained to connect with the stroke survivor, and impart advice about carer support, intensity and frequency of therapy if appropriate or asked by the stroke survivor. This intervention was the first iteration of what would come to be known as the Take Charge session.

2.5.2   Description of the Māori and Pacific Stroke Study

MaPSS was a multi-centre, randomised controlled trial testing two community-based interventions in Māori and Pacific people with stroke in New Zealand (M. Harwood et al., 2012). It was hypothesised that the Take Charge session might enhance the effect of the DVD – causing inspiring stories to be put into practice.

172 participants aged over 15 were randomised within three months of stroke to receive either:

- An 80-minute, professionally-made DVD of inspirational stories by Māori and Pacific people with stroke, or
- A Take Charge session: a structured risk factor and ADL assessment, designed to facilitate self-directed rehabilitation, or
- Both the DVD and the Take Charge session, or
- No intervention, but a sham visit that included handing out Stroke Foundation educational pamphlets (active control).

Inclusion criteria were all adults with stroke for whom ethnicity was coded as Māori or one of the Pacific Island groups and for whom discharge into the community after the stroke admission was considered realistic. There were no exclusion criteria.

Patients who were eligible were approached while they were in hospital. If they were interested in participating, Visit 1 was arranged. In total, participants were visited four times by research assistants. Each visit lasted 30 to 60 minutes.

Visit 1 occurred after two weeks but within three months of stroke. At this visit, the study was further explained and informed consent was obtained. Baseline information was also obtained, then the patient was randomised. What followed depended upon treatment allocation. Those in the control group received educational pamphlets. Those allocated to receive the DVD were provided with the video screen and DVD, and those allocated to receive only the Take Charge session had a subsequent visit arranged for 12 weeks after enrolment.

Visit 2 occurred 12 weeks after enrolment. This visit was primarily for delivery of the Take Charge session for those who were allocated to receive it (either TCS only or DVD + TCS), but all participants were visited to prevent confounding. Non-TCS participants had their educational pamphlet or DVD/video screens collected at this visit.

Outcome visits were Visits 3 and 4, which took place six and 12 months after enrolment respectively. These visits were conducted by the blinded data collector. Six-month and 12-month outcome measures were collected at these visits.

The primary outcome was self-reported, health-related quality of life measured by the Physical Component Summary (PCS) score of the Short Form 36 at 12 months.

80.8% of participants were followed-up at 12 months (n = 139). Results were strongly positive for the Take Charge session, which had an effect of 6.0 (95% CI 2.0 to 10.0) points higher on the SF-36 PCS, compared to no Take Charge session exposure. This was analysed per protocol. Somewhat surprisingly, the DVD had no effect on the PCS (effect estimate = 0.9, 95% CI -3.1 to 4.9) or any other outcome measures. Participants allocated to the Take Charge session were less likely to be dependent, with an odds ratio of 0.42 (95% CI 0.2 to 0.89) of having a modified Rankin scale score of > 2. Their carers also had lower (better) Carer Strain Index scores (-1.5, 95% CI -2.9 to -0.1).

Harwood's earlier qualitative work explored important issues for Māori following stroke, and this informed the development of the DVD and the Take Charge session. The results that the Māori and Pacific Stroke Study delivered: that the number needed to treat (NNT) with Take Charge was 6 to prevent one person becoming dependent, and that Take Charge significantly improved health-related quality of life – were unexpected and worth investigating further.

Some questions raised by MaPSS and its results will now be considered in detail.

The validity of the MaPSS results is affected by the small size of the trial. Lower than predicted recruitment resulted in 172 participants being enrolled over three and a half years. This was just over half of the initial target of 240 participants, which would have provided the study 80% power to detect a 4-point difference in the PCS. However, only 39-48 participants were exposed to each of the four arms.

The small study size not only increased the chance of Type I error, but practically also led to research clinicians at each site having fewer opportunities to put their training to use. Two sites enrolled fewer than ten participants. As feedback from the TaCAS research clinicians later revealed, it probably took at least ten 'goes' at delivering the

Take Charge session before research clinicians grew confident and comfortable with the process (Riley et al., 2017).

In addition, primary endpoint data in MaPSS were incomplete as completion rates of the SF-36 were low. Of 172 participants enrolled, only 139 were able to be followed-up at 12 months. Of these, only 117 completed the SF-36 (68% of total participants). It is possible that the final results may have been significantly altered if a sensitivity analysis had been performed, presuming results were negative for the 32% of missing data.

Participants were matched in age, gender and ethnicity at baseline. By chance, there was a slightly higher proportion of dependent participants (mRS > 2) in the control group compared with other groups at baseline. 46.1% of the control group had a baseline mRS > 2, compared with 37.5% in the DVD alone, 39.1% in the TCS alone, and 31.6% in the combined DVD and TCS groups. Likewise, the mean (SD) baseline Barthel Index (BI) was 15.9 (4.4) in the control group, compared with 17.7 (3.1) in the combined DVD and TCS group, and a mean BI of 16.7 (4.7) overall. While the difference between these figures was not statistically significant, there was a trend toward more individuals in the control group being dependent at the start, which may have contributed to the final proportion who remained dependent at the end of the study.

For the Take Charge intervention, most of the work was done during the verbal discussions between the research assistants, the participants, and their families, long before goal setting was brought up. Forming a connection, giving hope, empowerment, and helping the participant to see the stroke within the context of their own lives were all part of the conversations that took place in the Take Charge sessions during MaPSS. These conversations were not documented, hence the opportunity to operationalise the sessions and ensure some level of consistency was missed. Replication of each visit's discussions would have been difficult, but this is partly because the discussions would

have been tailored to each individual's concerns, and those of their family, if they were present.

Strengths of MaPSS included cultural safety of the research assistants (being of the same ethnicity as the participants, comprehensive research assistant training, and balanced baseline characteristics between groups. Because the research assistants had backgrounds in community health nursing, they had a minimum of five days of substantial group training prior to and during the study to ensure familiarity with rehabilitation concepts. Groups were also well-matched at baseline in all clinical and rehabilitation domains.

For the sake of reflecting on the content of the Take Charge session, it was worth noting that in unpublished feedback, goal setting was identified to be the most difficult component of the interventions. It seemed to be a new concept to most, if not all, participants and their families, and research assistants reported that it took significant time and explanation for people to take goal setting on board.

2.6   Consequences of the MaPSS results

The positive results of MaPSS were unexpected, given that the investigators had originally thought the Take Charge session might enhance the effects of an inspirational DVD of survivor stories. The DVD had no effect, but the combined Take Charge effect improved outcomes at the level of quality of life. It is important to reflect upon how and why these results came about. This section will illustrate two important downstream effects of the MaPSS study: first, a consideration of the knowledge gaps that the study

had left unanswered, and second, steps that would need to be taken to formalise the Take Charge session.

2.6.1   Gaps in the knowledge

The review of the literature of interventions for people with stroke in the community highlighted perceptual practice gaps and less than ideal outcomes from existing services.

At best, therapy-led rehabilitation may improve outcomes at the activity level by 1 point on the Barthel Index (BI) in one person for every 13 people who receive it (Outpatient Service Trialists, 2003). In the past, Wade estimated a change in score of four points on the BI as being clinically significant (D. Wade, 1992). Hsieh and colleagues used anchor-based and distribution-based methods to estimate an MCID of the BI to be 1.85 points (Hsieh et al., 2007).

Therapy-led rehabilitation and goal setting lack person-centredness in practice. Qualitative studies showed that efforts to make services person-centred are hampered by a number of factors: the attitudes and expectations of therapists and patients, breakdowns in communication about patient goals and desires, and system factors, including managerial influences such as emphasis on patient safety, defensive practice, and bed shortage, leading to lack of time for listening to patients (Bright et al., 2012; Rosewilliam et al., 2011).

Goal setting was the second component of the Take Charge intervention in the MaPSS. It is, therefore, curious that participants who received Take Charge showed a statistically significant improvement in activities of daily living and dependence. It is difficult to give goal setting sole credit for this outcome as there was little evidence from other quantitative research to support such a large positive effect. For example, the Cochrane systematic review on goal setting in rehabilitation only found weak evidence

of a small SMD in the outcome measure of health-related quality of life / self-reported emotional status, as measured most commonly by the MCS of the SF-36 (W. M. M. Levack et al., 2015).

There are two plausible explanations for this. First, it is possible that the first component of the Take Charge session, which explores and validates a person's sense of self, has the largest effect on improvement at the level of activity and participation. Alternatively, the distinct method by which the goals were reached might have 'lit a spark' with the culturally-appropriate research assistant, the patient, and their whānau. Goal setting in the Take Charge session was undertaken mostly by the person with stroke without significant, professional, rehabilitation input or suggestion from the research assistant. It is possible that Take Charge's novel, person-centred approach may have contributed to the Take Charge session's effectiveness at improving higher-level outcomes such as quality of life. One would hope that the results of the TaCAS study might shed further light on this approach.

There were key features of the Take Charge session that were different from previous interventions. The Take Charge session:

- Was loosely structured,
- Emphasised the importance of building rapport, connecting with the patient in person, and allowing them to establish their sense of self,
- Emphasised no education / training of the patient,
- Used a checklist, listening to the patient and asking questions to develop a 'rehabilitation plan' – thus identifying what is meaningful and important,
- Was delivered by a research assistant who was ethnicity-matched with the patient for greater cultural understanding.

Upon reflection, it was plausible that the Take Charge session acted on a mechanism of the psychology of motivation that is not well-studied nor widely understood by stroke physicians or neurologists. Qualitative research supported this idea. For example, in a study which used grounded theory to explore patient perceptions about recovery, the concept of Taking Charge was found to be a central theme in patients with arthritis, stroke, and chronic pain (McPherson, Brander, Taylor, & McNaughton, 2004).

Furthermore, the construct of grit may be relevant to those persisting with rehabilitation practice after stroke. Grit psychologist Duckworth defined grit as 'passion and perseverance for long-term goals despite setbacks, failures, and competing pursuits' (Duckworth, Peterson, Matthews, & Kelly, 2007). Gritty individuals tend to work toward one super-ordinate goal over a long period of time, with a large set of lower-order, alternative means to reach their highly-valued objective (Eskreis-Winkler, Gross, & Duckworth, 2015). The higher the number of lower-order options, the more committed the person is to the goal, and the greater their expectation that they will attain the goal (Kruglanski, Pierro, & Sheveland, 2011). It is possible that the Take Charge session increased levels of grit, and improving the design of the goal setting component should somehow incorporate this hierarchical goal framework (Figure 5)

Despite using tools such as goal setting within rehabilitation, the psychological and social components of the biopsychosocial model of health may often be overlooked. In his 2015 editorial of *Clinical Rehabilitation*, Wade argued that dominant model of care remains the biomedical model (D. Wade, 2015a).

In Wade's opinion, the dominance of the biomedical model has enabled behaviours and attitudes such as 'the sick role', in which a patient '*abrogate(s) any involvement in prevention or treatment*' (D. Wade, 2015a). Furthermore, he states that '*patients and their families expect therapy to make*

Figure 5. Hierarchical goal framework
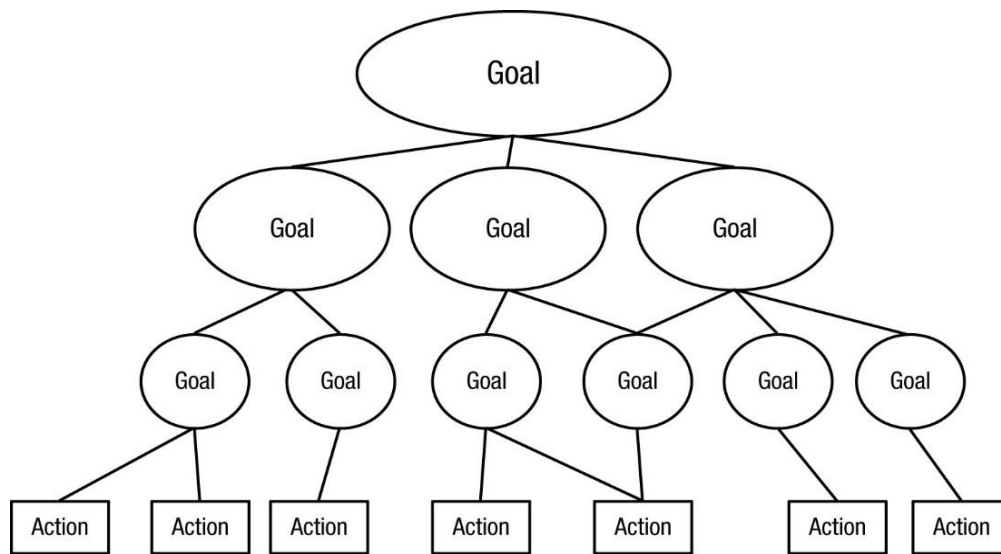
Reprinted from Self-Control and Grit: related by Separable Determinants of Success by A.L Duckworth and J. J. Gross, 2014, *Current Directions in Psychological Science,* p. 231.

things better, not recognising the importance of practice, learning etc.' In his view, rehabilitation '*involves the patient in a process of learning, which requires the patient to practice activities as much as possible. The patient must be actively engaged in rehabilitation, not a passive recipient of therapy*' (D. Wade, 2015a).

Therefore, it seems that regardless of their correctness, certain assumptions exist about the nature of those being rehabilitated. First, one assumes that for a person to actively engage with rehabilitation there needs to be some kind of reward-linked, "if-then" motivation for them to do so. This includes an implication that patients need to take responsibility to 'unlearn the sick role' in order to succeed in rehabilitation. The second assumption is that even when people are taking action or moving forward, they need guidance – without a direction from an expert, they will wander aimlessly and achieve little. The third assumption is that a patient has to 'learn to learn'. In his second

editorial of the same series, Wade states that '*the patient must want to learn... The patient must practice... The patient needs feedback on performance... the patient needs to take responsibility for learning.*' (D. Wade, 2015b)

Wade also states that rehabilitation involves the rehabilitation team in '*analysing the situation to identify all alterable factors that may reduce limitation on activities and social roles... and teaching the patient (and others) facts, skills, and self-management*' (D. Wade, 2015a).

However, based on clinical experience, I would argue that these assumptions overlook the self-awareness, intelligence, and intrinsic motivation that the patient brings to the team, and to the management plan for their own recovery. Innate psychological needs result in a person seeking their own ways of dealing with life events. It is paternalistic to presume that a patient cannot figure out that they might need to master certain smaller skills before they can undertake a desired activity, and to state that '*the patient may not wish to learn the more basic skill. Therefore it is vital to help the patient understand the link...*' as even infants and toddlers seem to be able to work this out on their own over time (D. Wade, 2015b). This coping ability comes under the umbrella term of 'personal factors' in the WHO-ICF, which is not always given the weight it deserves when one evaluates interventions or health systems (World Health Organisation, 2001).

Adding further credence to the alternative approach taken by the Take Charge session, were results from a large randomised controlled trial which were published after recruitment for TaCAS had commenced. The ATTEND trial tested a comprehensive caregiver-training intervention, and recorded a significant increase in therapy time in the caregiver-led groups compared with the control group (Lindley et al., 2017). However, outcomes at the end of the trial remained unchanged between groups (see Section 2.3.5,

page 77). More education, training, or face-to-face therapy time did not seem to hold the key to further improving outcomes.

After reflecting on the positive MaPSS result within the context of the literature review, the gaps in the knowledge were the following:

- Whether any particular features in the Take Charge session made the largest contribution to its positive effect on participation,
- Whether the effects of the Take Charge session could be replicated in other populations of people with stroke,
- Whether there would be a dose-response effect of the Take Charge session.

To explore the specific features of the Take Charge session which were central to its uniqueness and effectiveness, it was necessary to identify a pre-existing theory of motivation in the psychological literature which fitted the aims of Take Charge. This would give us a framework that would allow better understanding of the different components of the Take Charge session. The goal was to operationalise these components to improve Take Charge in its next iteration.

2.6.2   Seeking a supportive theory

The self-determination theory (SDT) of human behaviour and motivation best fitted the features of the Take Charge session that we felt were key for the patient:

- re-establishing identity and sense of self,
- articulating the things in life that gave meaning, and
- coming up with a plan for their recovery using their own skillset.

Psychologists Deci and Ryan developed SDT which states that 'conditions supporting the individual's experience of *autonomy, competence,* and *relatedness* foster the most volitional and high quality forms of motivation and engagement for activities' (Ryan &

Deci, 1985). Engagement for activities includes enhanced performance, persistence, and creativity. In addition, self-determination theory proposes that an environment in which any of these three psychological needs were unsupported or thwarted would cause a detrimental impact on wellness. Their studies also showed that relying on events that foster an external – perceived locus of causality, such as rewards, undermines intrinsic motivation.

Autonomy refers to the ability to act with freedom of choice. SDT argues that contexts can yield 'autonomous regulation only if they are autonomy supportive'. In other words, people will only voluntarily self-manage their rehabilitation if the environment supports them to do so. This is because, in order to take on board a regulation or task, people must be allowed to 'grasp its meaning and synthesise that meaning with respect their other goals and values'. This level of processing is only facilitated by a sense of choice, volition and freedom from excessive external pressure toward behaving or thinking a certain way (Kuhl & Fuhrmann, 1998).

In the context of rehabilitation, 'autonomy' confers autonomy over four particular aspects: what people do, when they do it, how they do it, and with whom they do it. Having this level of control, which is different to simply 'being independent', allows patients to do activities naturally and spontaneously when they feel free to pursue their inner interests.

Having autonomy over one's actions leads to mastery through deliberate practice. In other words, when one has the freedom to choose to do whatever they wish, they will do what they are good at (such as sudoku puzzles), or what gives them joy (such as gardening). Either of these things can be done repetitively, without strain, because of the nature of what they are – activities that are freely chosen by the person who is doing them. Doing the same thing over and over again is a form of deliberate practice, which

leads to mastery of the task. Mastery, or competence (as it was earlier known), relates to someone knowing what they are good at and being good at the thing they are doing. It encompasses the knowledge that they are skilful, which is knowledge that may be obtained by positive feedback or through internal positive feelings experienced when they are truly engaged with a task.

Another psychologist, Czikszentmihalyi described a similar concept of autotelic experiences, otherwise known as 'flow', as the state when people experienced the highest, most satisfying experiences in life (Csikszentmihalyi, 2014). In this state, the goal itself becomes self-fulfilling, and the activity is its own reward. The state of flow enables individuals to undertake deliberate practice, repeating the same task over and over, with focus and concentration, all the while making small adjustments to stretch themselves to a little bit beyond their current abilities. Over time, this leads to overall improvement.

The effects of rehabilitation could be enhanced by increasing mastery through these means, by stretching the body and mind in a way that would make the effort itself rewarding. To do so would take a shift in mindset, as therapists and the patient would need to believe that it was realistic and possible for the patient to achieve a higher-level goal. Deci and Ryan identified that perceived competence is necessary for any type of motivation (Deci & Ryan, 2000). In the context of rehabilitation, having mastery may enable the patient to feel competent when they undertake deliberate practice in something in which they are personally invested. They need to feel confident that they have the skills to make the most of their situation, their disability, and their life.

The significance of connectedness, or relatedness, was a question raised after MaPSS. It was unclear whether the Take Charge session's positive effect at the level of quality of life was related to a distinctive point of difference in Māori and Pacific culture: that,

unlike most European families, most Māori and Pacific people with stroke live in large, multi-generational households with members of their family or whānau. Self-determination theory argued that 'people initially perform extrinsically motivated behaviours because these behaviours are prompted, modelled, or valued by significant others to whom they feel attached or related' (Deci & Ryan, 2000). Conversely, the need to feel belonging or connectedness is centrally important for internalising extrinsically-motivated behaviours, such as taking on board goals that are suggested by other people.

Evidence in longitudinal stroke studies supports the idea that feeling connected to others plays a role in recovery. Colantonio and colleagues reported that having larger social networks was associated with fewer limitations in physical function and lower risk of institutionalisation after stroke (Colantonio, Kasl, Ostfeld, & Berkman, 1993). In a case-control study, Redfors and colleagues reported that living alone was associated with increased long-term mortality after ischaemic stroke in men under the age of 70 (Redfors et al., 2016). Feeling connected to others is an important psychological need in all human beings, and it is particularly critical to motivation.

The final component that is not explicitly named in the SDT, but which has emerged in the psychology literature especially in the business world, has been the notion of purpose. Increasingly, it has been recognised that those who live their lives in the service of a greater objective or cause can achieve more than simply having autonomy and mastery (Lee, Ready, Davis, & Doyle, 2017).

Deci, Ryan, and Niemiec asked college graduates about their life goals and followed them up after one to two years. Those who had goals that were personally meaningful and gave them a sense of purpose (for example, personal growth, community involvement, close relationships) reported higher levels of satisfaction and subjective well-being compared to those who set goals that were extrinsically-motivated (such as

goals related to gaining wealth or reputation). Furthermore, those who attained their extrinsically-motivated goals were found to have worse mental health scores as a result (Niemiec, Ryan, & Deci, 2009).

These findings suggested that satisfaction depends not merely on having goals, but on having the *right* goals, goals that come with a sense of purpose and personal growth. Within the hierarchical goal framework, these are higher-order goals which need to be worked toward via multiple lower-order goals. The larger the set of goal options that a person can come up with, the higher the chance they have of achieving their higher-order goal, and the less likely they will be set back by failure because they have already come up with alternative options (Eskreis-Winkler et al., 2015).

Setting rehabilitation goals within the context of a greater purpose that is meaningful to a patient may mean that rehabilitation teams will need to accept goals that are bold. These higher-level goals may be outside of what is deemed as 'realistic' or 'achievable' within the pedagogy of traditional goal setting. Rather than being dismissive of them, it may be more valuable to use higher-order goals as a final target and encourage the patient to come up with lower-order goals towards achieving their big dream.

During the course of this thesis, 'purposefulness' also appeared in rehabilitation literature, as a concept which the authors argued 'directly influenced and mediated individualised responses to health conditions' (Lee et al., 2017). Lee and colleagues described the essential role of purposefulness within the biopsychosocial model, its significance to the 'personal factors' component of the WHO ICF, and its role as a 'higher ideal' as a universal characteristic of all human beings. Their recommendation that clinicians pay more attention to purposefulness and 'who' their client truly is – including their desires, values, and needs – echoed the first three pages of the Take Charge session booklet we developed (see Section 2.6.3 and Appendix).

We devised a simple measure which attempted to determine whether these SDT concepts contributed to the effect of the Take Charge session. We named this measure the AMP-C, which stands for autonomy, mastery, purpose, and connectedness. The first three items were grouped together because they seemed to originate intrinsically 'within' a person, while how connected they felt to others at times depended upon external, extenuating circumstances. The AMP-C is detailed in Section 3.6.11, page 166.

2.6.3   Formalising the Take Charge Session

In MaPSS, the Take Charge session was loosely structured using a checklist to make sure that issues important to the patient were covered in the session. Their self-directed rehabilitation plan was then derived from this discussion. For the Take Charge session to be tested further and potentially used in clinical practice, it was important to make the features that separated Take Charge from other interventions definite and visible (see Table 2).

Using self-determination theory as a guide, we transformed the checklist into a booklet with gaps that could be filled by patients (see Appendix). Some features in the booklet also drew upon other sources such as 'My Best Day', an idea which was borne from clinical experience in palliative care.

Table 2. Differences between traditional rehabilitation and the Take Charge Session

Traditional rehabilitation	Take Charge Session
Structured	Loosely structured
Time-limited session	Time unlimited
A generic plan tailored to the individual	Completely personal
Clinician as teacher/coach/expert	Clinician reflects the person's own thoughts
Control with the clinician	Control with the person
Focus on what is doable/realistic/achievable	Focus on what the person wants
A complete plan of future action at the end of the assessment	No plan is OK

The first page of the booklet provided space to note down how the stroke had affected the person, and who they really are as they see themselves. The second page had a space to write down their hopes and their fears. The third page asked them to imagine their best day and to draw or write what they visualised. It was hoped that these three pages would help the patient:

- Re-establish a sense of self,
- Identify the things most important to them in life, which gave their life purpose and meaning, and
- Think about the skills they had, the things they enjoyed doing, and the potential barriers that they felt might impede success.

It was envisaged that these pages would be completed in a setting that would promote utmost autonomy, where the patient could say, think, and write down whatever they

wanted, with as little interference as possible from other people. This feature of the Take Charge session would be emphasised when training future Take Charge facilitators. Ensuring participant autonomy was also one of the reasons that we kept Take Charge as a home/community-based intervention, instead of opting to test it in an inpatient setting.

The final pages of the booklet provided a space for goal setting, where goals of any level would be encouraged. Once these were written down, the person had a space to write down how they could break the goal down into smaller goals or steps. Each page would have a different heading such as Physical, Financial, etc. that would correspond with the initial rehabilitation checklist from MaPSS.

In addition to the booklet, we developed a training manual. The manual documented the objectives and steps in training and described how and why we thought the Take Charge session would work. It also highlighted the key features of the session and provided examples and roleplays that trainees could follow that would give them a feel for how to facilitate the session themselves. This would allow full transparency and reproducibility of the Take Charge session, in the training of facilitators and how to run the session. The booklet and the manual also enabled planning for a second randomised controlled trial, in which Take Charge would be tested in a different group of people with stroke, facilitated by a new group of research clinicians. This is the present study, the Taking Charge After Stroke (TaCAS) study.

2.7   Thesis statement

There is evidence that existing interventions may be further enhanced by a novel intervention, the Take Charge session, leading to improved outcomes for patients with stroke in the community.

This thesis describes the Taking Charge After Stroke (TaCAS) study, a trial that was designed to determine whether:

- The Take Charge session is effective in a group of non-Māori, non-Pacific people with stroke, and

- Whether two 'doses' of the intervention is more effective than one.

3 Method

This chapter outlines the methodology of the Taking Charge After Stroke (TaCAS) study. This study tests whether the Take Charge session, a novel, community-based intervention, can improve health-related quality of life for people with stroke.

A substantial part of this chapter has been previously published in BMJ Open as the TaCAS study protocol (Fu, Weatherall, & McNaughton, 2017). Acknowledgements are made to the other authors, Dr Harry McNaughton and Prof. Mark Weatherall, who provided feedback on the original manuscript. The copyright license for this article is supplied in the Appendix.

The Participant Information Sheet, Consent Form, all source data forms, and a copy of the Take Charge Session booklet are also included in the Appendix. The Stroke Foundation pamphlets provided to the control participants can be accessed at https://www.stroke.org.nz/free-resources.

3.1   Hypotheses

The hypotheses to be tested are as follows:

First, in a population of adult, non-Māori, non-Pacific people with stroke discharged to community living, not fully recovered from their stroke, the Take Charge intervention improves health-related quality of life at 12 months after stroke.

Second, in the same population, exposure to two Take Charge interventions has a greater improvement effect on health-related quality of life compared to exposure to one Take Charge intervention.

3.2   Population / Setting

TaCAS was proposed to be a prospective, single-country, multi-centre, parallel-group, randomised controlled trial of 400 patients with a new diagnosis of acute stroke. Patients were screened for eligibility by local researchers in seven New Zealand hospitals using the inclusion and exclusion criteria listed.

Inclusion criteria:

- Non-Māori, non-Pacific adults > 16 years of age with acute ischaemic stroke or intracerebral haemorrhage (WHO definition)
- Discharged from hospital to non-institutional, community living situation
- Not fully recovered, i.e. mRS ≠ 0

Exclusion criteria:
- Inability to provide informed consent
- Unlikely to survive beyond 12 months
- Dependent pre-stroke, i.e. prior to stroke mRS was ≥3

The screening researcher could either be the stroke nurse or doctors of the stroke team, or the principal site investigator, or the local research clinicians, depending on the centre. In hospital, this researcher explained the study and provided a participant information sheet to eligible patients and determined their stroke severity using the Barthel Index (BI) at days 5-7 after stroke. In the presence of conditions such as aphasia

or cognitive impairment, the patient's ability to understand the study—and therefore to consent—was determined by the screening researcher. Permission was sought for follow-up by telephone after discharge.

The hospitals were geographically dispersed and ranged from semi-rural (secondary) to regional (quaternary) units. The trial sites are listed in Table 3. All public hospitals in Aotearoa New Zealand are governed by 20 district health boards (DHBs). Healthcare is free to all New Zealand residents.

Māori and Pacific people with stroke were excluded from TaCAS as there would have been a one-in-three chance of randomising these patients to a control arm. This was considered unethical given that MaPSS had demonstrated that this population would benefit from the Take Charge intervention. We were also interested to know whether Take Charge would work in a different population who did not share the same sociocultural characteristics as Māori and Pasifika. Furthermore, finite, limited resources meant that in this study, where the main goal was generalisation, excluding Māori and Pasifika people with stroke was the most effective and ethical use of resources.

Patients received inpatient diagnostic procedures, treatment, and rehabilitation as per local practice, not influenced in any way by being involved in the study. Patients who expressed interest in participating were followed until their date of discharge. Those discharged into non-institutional, community living (not rest home or hospital-level care) were telephoned within two weeks to arrange a baseline home visit with a research clinician (RC). The RC was either a nurse, physiotherapist or occupational therapist, who was trained in the delivery of the Take Charge session. The RC had to complete this visit within a 16-week window from the date of stroke, which allowed for time spent in inpatient rehabilitation.

Table 3. Study sites and hospitals

Principal Investigator	Centre	City	District Health Board
Dr Harry McNaughton	Wellington Regional Hospital	Wellington	Capital and Coast
Dr Tom Thomson	Hutt Hospital	Lower Hutt	Hutt Valley
Dr Carl Hanger	Princess Margaret / Burwood Hospital	Christchurch	Canterbury
Ms Anna McRae	Auckland City Hospital	Auckland	Auckland
Dr Geoff Green	Middlemore Hospital	South Auckland	Counties Manukau
Dr Anna Ranta	Palmerston North Hospital	Palmerston North	MidCentral
Dr John Gommans	Hawkes Bay Hospital	Hastings	Hawkes Bay

3.3   Randomisation visit (V1)

Patients were telephoned a week after discharge, and if they were keen to participate, an appointment was made for the RC to visit the person's home. This was the first visit (V1), which was received by all participants.

The structure of V1 was as follows:

1. Meet participant and explain the study in detail, answering any questions
2. Assess eligibility to participate (ethnicity, mRS ≠ 0)
3. Obtain informed consent
4. Complete baseline assessment
5. Open randomisation envelope
6. Depending on allocation, either give Stroke Foundation pamphlets or proceed with Take Charge session

Informed consent, based on the International Conference on Harmonisation Good Clinical Practices (ICH-GCP) guidelines, was obtained prior to randomisation (ICH Expert Working Group, 1996). No one consented on behalf of participants because proxy consent was not permitted by the ethics committee. Once the participant was consented, the research clinician randomised the participant to either one of the two interventions (TCS 1 or TCS 2) or to control by opening a sealed, opaque envelope containing allocation. An independent statistician (see Section 3.11, page 177) was responsible for the computer-generated allocation sequence used to create the envelopes, which were consecutively numbered and delivered to each site in blocks of 18.

Prior to randomisation, all participants underwent a baseline assessment, which included demographics, post-stroke dependence measured by the mRS, activities of daily living by the Barthel Index (BI), extended activities of daily living by the Frenchay Activities Index (FAI), health-related quality of life by the Short-Form 12 (SF-12v2), depression by the Patient Health Questionnaire-2 (PHQ-2), activation by the Patient Activation Measure (PAM), how well intrinsic psychological needs were being met (AMP-C), as well as stroke-related risk factors and medications. Current support, outpatient rehabilitation service involvement and work situation were also recorded. After the baseline assessment, but at the same visit, participants received their allocated intervention: either a TCS or control. If allocated to two sessions, an appointment was made with the participant for the second visit (V2) for approximately six weeks after V1.

The study flow chart is presented in Figure 6.

Figure 6. TaCAS study flowchart

Initial visit by research clinician

(6-16 weeks since stroke)

- Informed consent
- Baseline assessment
- Randomisation

Control

Stroke Foundation pamphlets

TCS 1

TCS

TCS 2

TCS

V1

Second visit by research clinician

(6 weeks after initial visit)

TCS

V2

Month 6 Follow-Up

(± 14 days)

- mRS, BI, FAI, SF-12v2, EQ-5D-3L, PHQ-2, PAM, CSI
- Medications
- Rehab contact / hospitalisations
- Work / income information

Month 12 Follow-Up

(-28 days / + 42 days)

- mRS, BI, FAI, SF-36, EQ-5D-5L, PHQ-2, PAM, CSI
- Medications and adherence
- Rehab contact / hospitalisations
- Work / income information

127
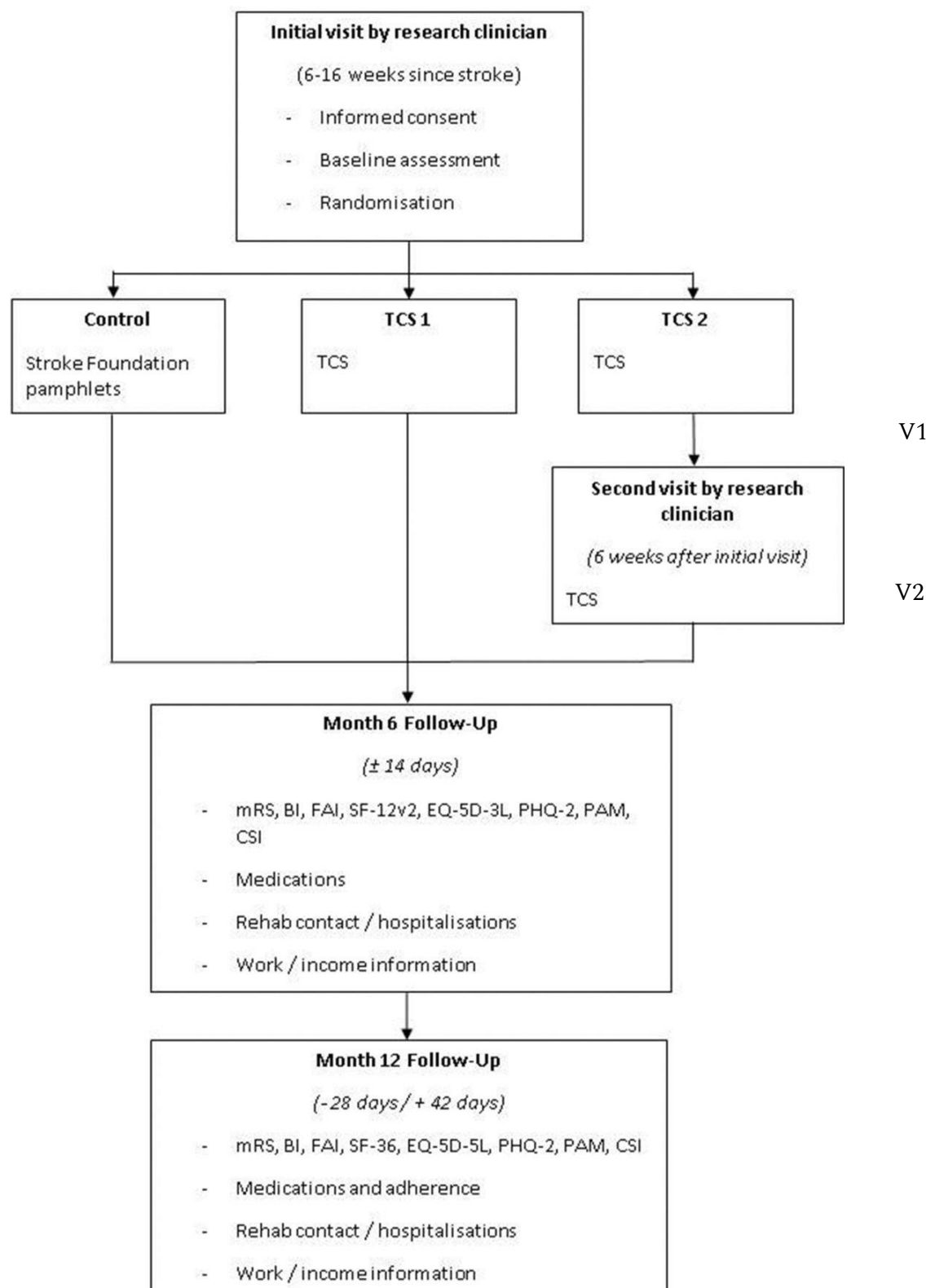
3.4   Control arm

After the baseline assessment, participants who were randomised to the control group received educational pamphlets produced by the Stroke Foundation of New Zealand (see www.stroke.org.nz/free-resources). The topics of the pamphlets were: 'What is Stroke?', 'Reduce your risk of stroke', and 'Stroke Information for Family, Whānau, and Friends.' They covered risk factor management and common issues following stroke. The research clinician (RC) left these pamphlets with the participant to keep for good. All aspects of routine stroke care, in particular, contact with rehabilitation services, were unchanged by participation in TaCAS.

3.5   Intervention: the Take Charge Session (TCS)

The Take Charge session was first introduced in the chapter describing the Māori and Pacific Stroke Study (MaPSS). In this present study, while it was essentially the same intervention based on the identical principle of Taking Charge, a few improvements had been made, such as comprehensive training, to allow it to be better operationalised (see Section 2.6.3, page 117). A detailed explanation of the Take Charge session used in TaCAS follows.

3.5.1   Training research clinicians to facilitate the Take Charge session

The Take Charge session was delivered to the participant in their home environment by a trained RC. In TaCAS, our RCs lived and worked in each centre for which they were responsible. They were skilled health professionals with different backgrounds: research nursing, physiotherapy, stroke nursing, and inpatient rehabilitation nursing. Only the

MRINZ research nurses took on TaCAS full-time; the others split their time between TaCAS and their clinical roles.

We were aware that there was a risk of possible contamination by RCs who held clinical and research roles. To minimise this, the RCs ensured that they actively removed themselves from the inpatient care of a potential participant and referred the patient to another member of the multidisciplinary team. If the RC had already been directly involved with the potential participant's inpatient care, they referred the person to another RC to undertake the visits for TaCAS. In addition, the study investigators aimed to recruit the majority of participants from sites where the RCs were research nurses only with no clinical roles, i.e. Wellington, Hutt Valley, and Counties Manukau (see Table 7, page 181).

Before recruitment or participants began, all the RCs received a minimum of eight hours of training, delivered by the lead investigator, Dr Harry McNaughton, and the study manager, Tanya Baker. Central to this training was the idea that the Take Charge session is not the same as traditional goal setting and rehabilitation. These core differences are highlighted in *Table 2*, page 118.

Particular emphasis was placed on the importance of the RC refraining from offering suggestions and advice to the participant during goal setting. RCs were actively discouraged from suggesting goals so that the focus remained on what the participant wanted, rather than what was perceived by the RC to be doable. RCs were trained to encourage participants to ask and answer their own questions, and to form their own ideas.

Time spent listening to participants was also emphasised, in particular, the importance of allowing participants to consider and express their hopes, fears and priorities. RCs

were provided with a list of sample reflective statements and questions that could be used in lieu of dispensing advice. Role play was used to familiarise the RCs with the way of thinking and language used. These techniques were employed to ensure that new ideas and thoughts during the session came directly from the participant.

The TCS booklet (see Content of the Take Charge session 3.5.2 and Appendix) was provided to the RCs. They were asked to think about and complete each page for themselves to get a feeling for what the participants would experience.

The training day also covered ICH-GCP in clinical trials, namely informed consent and source documentation. The RCs were provided with copies of the source data forms and instruments used in the study and trained in how to complete these.

After recruitment began, two teleconferences were held for the RCs to feedback, discuss, and problem solve with the study coordinator and other members of the study team. The RCs made suggestions for minor modifications to the source data forms, and these were noted, submitted to, and approved by, the Health and Disability Ethics Committee (HDEC). Further support and training for RCs were provided on an ad hoc basis.

3.5.2   The content of the Take Charge session

The Take Charge session was divided into two main parts, guided by the workbook (see Appendix). The RC could assist with writing in the workbook if the participant was unable to write. If the participant was unable to think of any responses, the pages could be left blank. The purpose of the workbook was to put in writing the concepts that were important in self-determination theory, using simple drawings and diagrams as a guide.

The first three pages stimulated the person to think of the things which were most meaningful and important in their lives. The first page consisted of two circles

connected by a series of arrows, depicting one circle transforming into another. The circle on the left was labelled "My Stroke" and participants were asked to write down all the ways the stroke had affected them. The circle on the right was labelled "Who I Really Am". In this circle, participants wrote down all the words they could think of that described themselves.

On the second page, participants were asked to imagine their hopes and fears. These were written in three spaces under separate headings. This exercise gave space for the participant to have their dreams heard in a setting where they would be comfortable being bold, rather than concerned that their hopes could be dismissed or described as unrealistic or unattainable. It also allowed them to name the things they were most afraid of so that they could see what their obstacles or setbacks might look like. Sometimes, these fears could be thoughts the person had which they may not have been given permission to articulate.

For people who struggled to express their hopes, by expressing fears, it was possible to acknowledge the opposite was a 'hope'. For example, *"I'm afraid I won't be able to go back to work full-time"* is really an expression of *"I really hope that I can go back to work full-time"*. If the person was uncomfortable about sharing their hopes and fears, the space could be left blank. The idea was that just thinking about these concepts, or writing about them in their own, private time, could be a helpful first step for the participant.

The third page was titled 'My Best Day' accompanied by small drawings of stick people doing various things. The participant was invited to visualise their best day and describe what it would look like. Crayons were supplied to allow a different medium of expression. Alternatively, participants could write down the highlights of their imagined best day. If they were unable to write, the RC could write down the things they described.

The second section of the TCS was goal setting, which was guided by headings at the top of each page. Headings for goals included: Physical Needs, Communication, Emotional Issues, Information Needs, Financial Issues, My Support Network and Stroke Prevention. Participants were encouraged to think about goals that they wanted to achieve and to write these down. Then, they were asked to suggest ways of breaking down these goals into smaller goals or steps which they would be comfortable with undertaking. It was entirely acceptable for pages to be left blank if the participant did not have any goals that fell within the scope of the heading, or if they could not think of any specific goals at the time of the visit.

3.5.3   The timing of the first visit (V1)

The window of timing for V1 was wide, between one to 16 weeks from stroke, and rarely up to 18 weeks if the scheduled 16-week visit was cancelled for any reason. The window was wide because the Copenhagen Stroke Study showed that functional recovery was strongly related to initial functional disability, and best ADL function was only reached within 17 weeks in patients with initially very severe disability (Jørgensen et al., 1995). We considered that the ideal time for people to be visited was *'as early as possible in the community phase of stroke'*. Using this definition as a guide allowed potential participants to advise the study team if they preferred their first visit at a later date. Reasons for postponing included fatigue, feeling too overwhelmed to manage visitors, and frequent outpatient appointments with therapists or medical specialists in the initial weeks after discharge home.

On the other hand, the ideal minimum time between index stroke and randomisation was thought to be one week, to allow for inclusion of potentially eligible patients who had been seen in the emergency department or the TIA clinic and discharged. The main requirement was that these patients had not fully recovered (mRS ≠0) at the time of

randomisation. By approaching patients early, we were able to include people with milder deficits (such as homonymous hemianopia) before they had fully recovered. It was important that these patients were not excluded because milder impairments could still significantly impact on participation restriction and social function.

Therefore, the reasons for accepting this wide range in timing for the first visit were:

- The recognition that recovery from stroke was not solely physical, and functional recovery could take months to years, allowed us an upper limit of 16 weeks.
- Take Charge was a person-centred intervention, and being in their home environment was a basic part of increasing the patient's sense of self. Needing time in rehabilitation in order to get home should not be an exclusion.
- The intervention had been shown to be effective when delivered at approximately 12 weeks after stroke in MaPSS, which reassured the study team that randomising participants up to 16 weeks after stroke would not dampen its effect.

3.6   Outcomes

Participants were followed six months after stroke with a questionnaire delivered by telephone, post or the internet. An outcomes assessor masked to treatment allocation gathered all the questionnaire information and attempted to confirm incomplete responses by a telephone call. At 12 months after stroke, the outcomes assessor visited all participants in person to complete follow-up. Before the visit, participants were reminded not to reveal their allocation and to keep study materials received at the initial visit(s) hidden.

Table 4 on page 135 shows the primary and secondary outcomes as well as the predefined subgroup analyses. The timing and components of each assessment are shown in Table 6, page 171.

The primary outcome was physical health-related quality of life as determined by the PCS of the SF-36 at 12 months after stroke. The TaCAS study used quantitative instruments as baseline and outcome measures. The following section will describe the instruments and explain their reasons for inclusion in the study.

Within stroke rehabilitation alone, there are many instruments that are used to measure multiple different outcomes. Given the lack of general consensus on the best selection of measures to best address the needs of patients, caregivers, physicians, and researchers, it is essential to outline the considerations taken when selecting which measurement instruments to use.

Table 4. Outcomes of the TaCAS study

Primary outcome	PCS of the SF-36
Secondary outcomes	At six months after stroke:
	PCS of the SF-12v2
	ADL by Barthel Index (BI)
	Extended ADL by Frenchay Activities Index (FAI)
	Level of function by modified Rankin Scale (mRS)
	Depression by Patient Health Questionnaire-2 (PHQ-2)
	Health-Related Quality of Life by EuroQol EQ-5D-5L
	Carer strain by Caregiver Strain Index (CSI)
	Contact with rehabilitation service
	Hospitalisations
	At 12 months after stroke:
	Face-to-face assessment of:
	BI, FAI, mRS, PHQ-2, PAM, EuroQol EQ-5D-5L, CSI, rehabilitation contact or hospitalisations
Proposed subgroup analyses	Age above or below 75
	Use of fluoxetine at baseline
	Presence of a significant communication problem
	Presence of a significant cognitive problem
	Gender
	Whether the participant was living alone
	Presence of a support person
	Ischaemic vs haemorrhagic stroke
	Receipt of thrombolysis
	Receipt of thrombectomy
	Treatment in a tertiary centre
	Recruitment site
	BI at baseline categorised as Mild, Moderate or Severe
	Slope relationship with AMP-C sum

3.6.1 The International Classification of Functioning, Disability and Health

The International Classification of Functioning, Disability, and Health (ICF) is a classification system released by the World Health Organisation (WHO) in 2001. Originally published in 1980 as the International Classification of Impairment, Disability and Handicap (ICIDH), it has since been revised several times.

This model conceptualises the experienced consequences of any disease from biological, personal, and social perspectives. Human functioning and disability are separated into three levels: the level of the body or body parts (*body functions and structures*), the level of the whole person (*activities*), and the level of the whole person functioning within his or her environment (*participation*) (WHO, 2001b). Disability involves dysfunction at one or more of these levels: symptoms and signs (or impairment), activity limitation (formerly referred to as disability in the ICIDH framework), and participation restriction (formerly referred to as handicap).

When deciding upon an outcome measure in neurological rehabilitation, it is crucial to consider which level of disability is being measured by the scale. For a classification system or instrument to be useful for research purposes, the categories and concepts within it should be measurable, with clear and well-defined boundaries.

The ICF framework can be used to place outcome measures into one of the three categories depending upon what it is they purport to measure. At each level, the disease or condition that is being measured can affect the person in different ways. Furthermore, the number of external factors not necessarily related to health increases as one moves away from body structure and function towards participation and life satisfaction. This can make instruments at the participation level much longer, more complex, and the concepts more difficult to measure. Figure 7 shows the relationships between each level of function, the health condition, and contextual factors.

136

Figure 7. The ICF model of function and disability
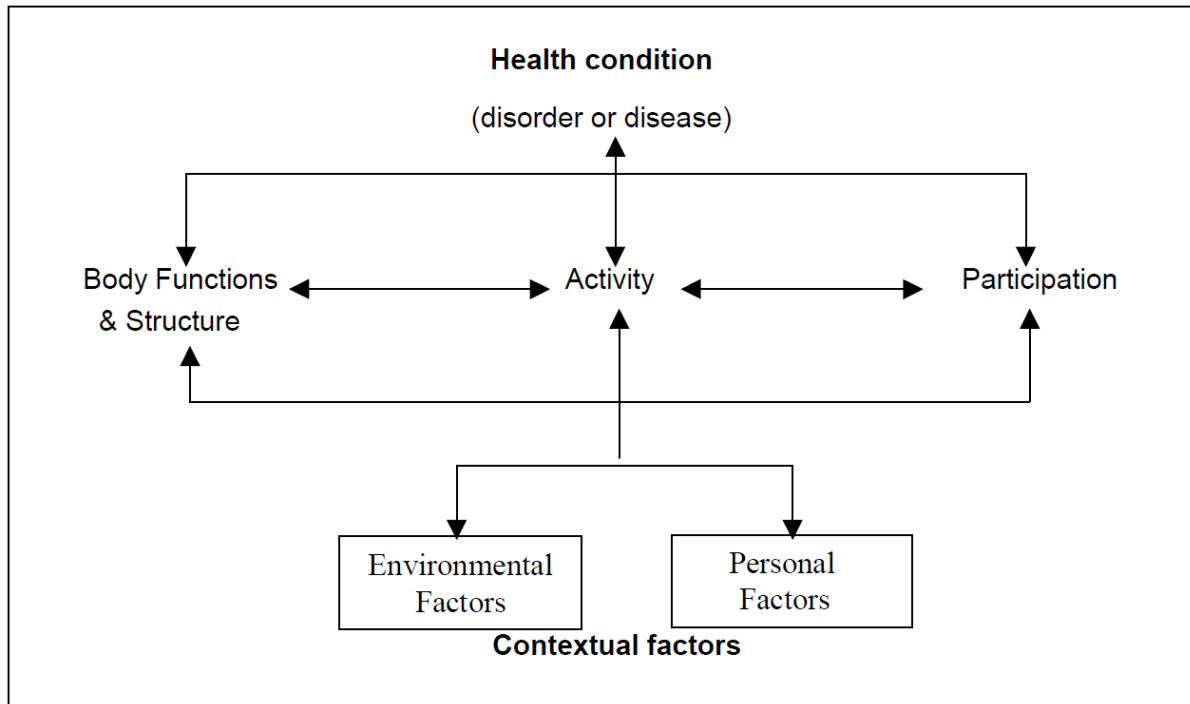
Body functions and structures encompass the disease affecting an organ or organ system within the person's body. This is the level where medicine is focused on diagnosing and treating disease. Different pathologies are further classified in the International Classification of Diseases (ICD) of the WHO. In the context of this study, the pathology is the index stroke.

Impairments are problems in body functions or structure, such as significant deviation or loss (WHO, 2001a). Within medicine, they are often referred to as 'symptoms and signs'. Neurological impairments include weakness of a limb, sensory disturbance, or ataxia. The National Institute of Health Stroke Scale (NIHSS) is an example of a scale that measures stroke at the level of impairment, translating specific components of the neurologic examination into a 15-item scale (Brott et al., 1989).

Activity limitation is how the condition manifests within the context of the person and their immediate environment. The ICF defines activity limitation as "difficulties an individual may have in executing tasks or actions". Examples of activity limitation include difficulty with mobility or needing help with personal care. The Barthel Index measures dependence on others for basic activities of daily living, combining personal care and mobility in a scale that measures at the level of activity limitation (Mahoney & Barthel, 1965).

Participation restriction is often the level which determines the true severity of illness, as it refers to the social and societal consequences of the disease experienced by the person. Examples of participation restriction include loss of employment, social isolation, or change in family roles, arising as a consequence of stroke.

While impairment and activity limitation are judged within a reference frame of normality against the entire population, participation restriction can only be measured relative to the person's own life, and the things in their life which are normal to them. Because there is no standard metric against which one can evaluate the severity of participation restriction, it is a difficult thing to measure.

As mentioned earlier, in 2001, the WHO-ICF superseded an earlier classification system, the International Classification of Impairment, Disability and Handicap (ICIDH). In his book, Measurement in Neurological Rehabilitation, Wade recommended that handicap should be considered as 'referring to the change in a patient's quality of life...' or '...to equate handicap with loss of autonomy or freedom of action' (D. Wade, 1992). The term 'handicap' is archaic, but participation restriction has these sentiments in common. The Frenchay Activities Index (FAI) measures at the level of participation restriction by evaluating a person's frequency of performing extended activities of daily living (EADL), including social, vocational and leisure activities.

The ICF model also includes two important elements that affect the complex phenomena of disability: environmental and personal factors. Environmental factors include barriers and facilitators in urban design, justice and law, and attitudes within society – all of which impact an individual's ability to undertake in activities and participate in life. Personal factors include age and gender, but also intrinsic influences such as coping mechanisms, cultural background, upbringing, and self-esteem.

The ICF views disability from medical and social standpoints. Therefore, the framework of disability allows interventions to be targeted to improve specific problems at each level. Table 5 illustrates examples of interventions and prevention measures provided in the WHO guide (WHO, 2001a).

Table 5. ICF - How the three different levels of disability are linked with three levels of intervention (World Health Organisation, 2001)

	Intervention	Prevention
HEALTH CONDITION	Medical treatment / care Medication	Health promotion Nutrition Immunisation
IMPAIRMENT (body)	Medical treatment/care Medication Surgery	Prevention of the development of further activity limitations
ACTIVITY LIMITATION (person)	Assistive devices Personal assistance Rehabilitation therapy	Preventive rehabilitation Prevention of the development of participation restrictions
PARTICIPATION RESTRICTION (social function)	Accommodation Public education Anti-discrimination law Universal design	Environmental change Employment strategies Accessible services Universal design Lobbying for change

Figure 8 on page 142 summarises the different levels of the ICF we considered in the context of stroke.

Selecting the best outcome measures

After reviewing 51 acute stroke interventional trials, Duncan and colleagues made several recommendations about outcome measures based on their findings (P. Duncan, Jørgensen, & Wade, 2000). Their findings were that there was significant heterogeneity of selection of outcome measures, of selection of timeframes to measure outcomes, and of enrolled patients without adequate adjustment for expected outcomes. They recommended the following:

- All interventional stroke trials should use the WHO-ICIDH (now the WHO-ICF) as a systematic framework for assessing outcomes.
- In acute stroke trials (especially when testing new medications or procedures), impairment measures should not be the primary outcome because patients are more concerned with activity.
- In studies enrolling patients with mild to moderate stroke, researchers must consider recovery beyond ADL. Instruments measuring at the level of participation are simple and relevant to the patient, and may be more sensitive to between-group differences.
- All outcome measures should have established psychometric properties (reliable, valid, and sensitive to change), and should have been tested in individuals with stroke.
- In acute stroke trials, measurement of primary outcomes (neurological and functional) should occur at six months, especially if patients with severe stroke are included.

- Measurement of participation should take place when the 'patient's social condition has stabilised'.

All of the above recommendations were taken into consideration when choosing the outcome measures for the present study.

As a community-based intervention delivered at up to 16 weeks after stroke, the Take Charge session was not expected to have any impact at the impairment level. The Copenhagen Stroke Study showed that recovery of motor impairment is almost complete by 12 weeks after stroke (Jørgensen et al., 1995). Furthermore, Take Charge is aimed at improving function, and measures of impairment can not capture the importance of function to a person. A simple example of this is that the ability of a guitarist with stroke to continue to play for pleasure far outweighs any supposed measurable changes in grip strength or finger movement.

Therefore, the standard we set for the Take Charge session to be deemed an effective rehabilitation intervention was that it needed to exert its effect primarily at the level of participation, social function, and quality of life. Because consequences at these levels impact a stroke survivor's life in the long term, it was important to us that a successful intervention could effect change at these levels.

The International Classification of Functioning, Disability, and Health (ICF)
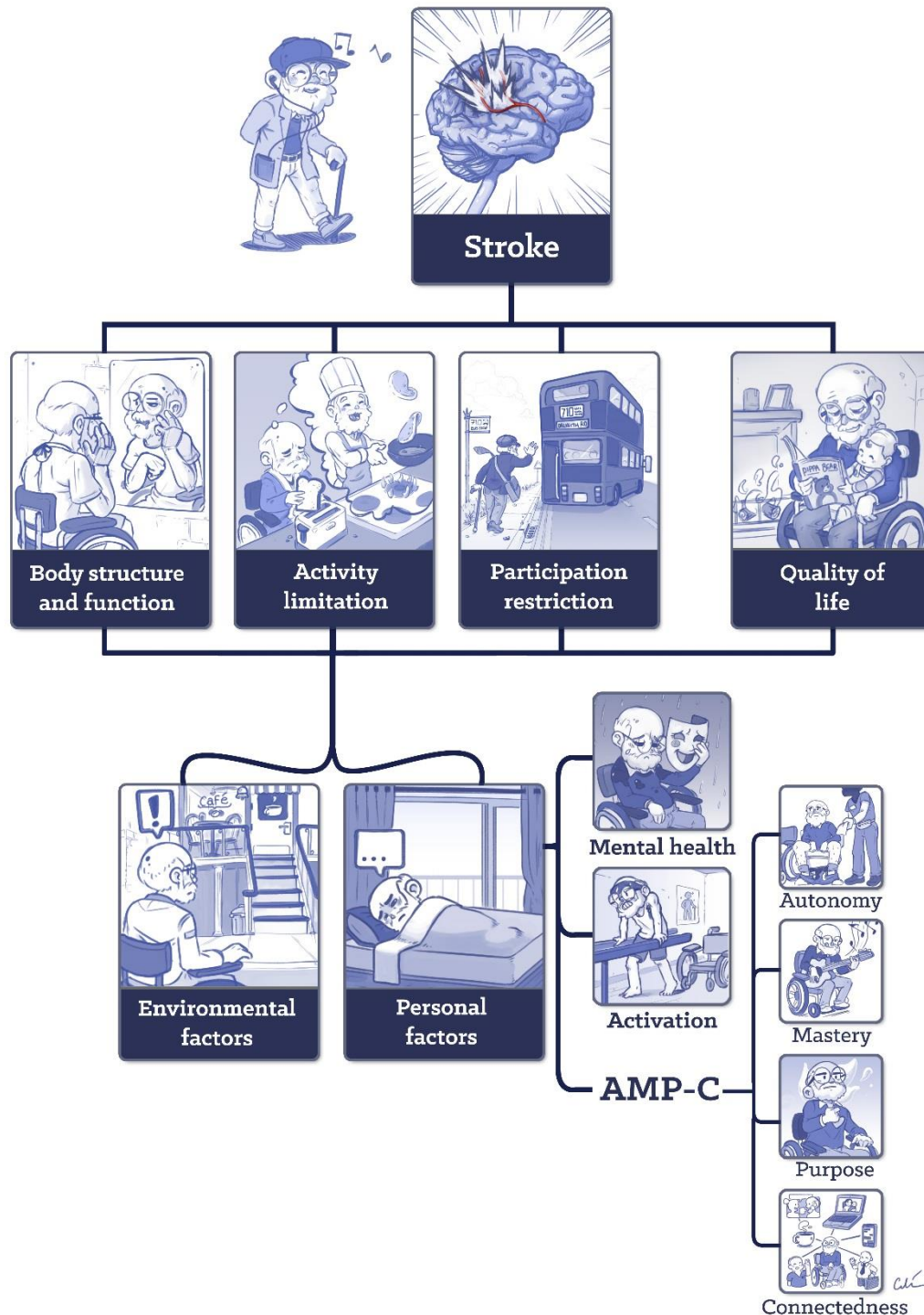
Figure 8. Conceptual illustration of how the ICF relates to stroke

Illustration by Dr Ciléin Kearns, Medical Illustrator at the Medical Research Institute of New Zealand

3.6.2   The Short Form 36-item Questionnaire

The primary outcome measure for the present study is the Physical Component Summary score of the Short Form 36-item questionnaire, version two (PCS of the SF-36v2). The SF-36v2 was chosen as the main instrument in TaCAS because it encapsulates a person's overall health-related outcomes based on self-report, and best determines health-related quality of life.

Overall, the SF-36 is more comprehensive and has more depth than the FAI, which also measures outcomes at the level of participation. The SF-36 measures an overall health state and incorporates multiple health domains, including physical and mental health. Results can be easily compared against population norms and across multiple health/illness states, including between different conditions. Furthermore, it has sound psychometric properties, and data can be transformed into cost-utility units (Frieling, Davis, & Chiang, 2013). The latter feature could be used to conduct a cost-effectiveness analysis, which would be essential for convincing health authorities to consider implementing a novel intervention.

The SF-36 was initially developed based on data gathered from two large-scale population studies of health services: the RAND Health Insurance Experiment, and the Medical Outcomes Study in the United States (Brook et al., 1984; Stewart & Ware, 1992). The former study showed that self-reported data could be used to construct scales that were valid and reliable. These scales could be used to obtain further high quality data about changes in health status in the general population. The latter study used these derived scales as questionnaires to measure health status in over 23,000 patients and across about 40 different health concepts. The principal investigator from the Medical Outcomes Study selected items from the standardised questionnaires to be included in the development of the SF-36. The SF-36 was developed with a view to reducing

responder burden while maintaining a comprehensive assessment (J E Ware & Sherbourne, 1992).

The SF-36 was subsequently translated and tested in the International Quality of Life Assessment (IQOLA) project which included data from 14 countries in 1993. International interest in its use continued, and as of 2008, there were at least 109 country/language translations. The SF-36 continues to be used by governmental organisations to assess national health status, and by researchers of various acute and chronic health conditions to evaluate interventions.

In 1996, version 2.0 of the SF-36 was made available, which improved on deficiencies in the original version (Maruish, 2011). These included wording changes of some questions and increasing the responsiveness of some scales by having greater levels of responses, for example, having five possible responses rather than two (Maruish, 2011).   The SF-36v2 is one of the most widely used instruments for measuring quality of life in the world (de Haan, 2002). Researchers also developed the Australian New Zealand version of the SF-36v2, modifying the language slightly to suit our Antipodean context (Frieling et al., 2013). The Australian/New Zealand version of the SF-36v2 is used in the present TaCAS study. For the sake of readability, from this point onward I will use 'SF-36' to refer to the entire instrument, including the updated second version.

The SF-36 consists of 36 questions with discrete Likert responses. It can be completed either by the respondent either on their own or with an interviewer. Each response has a different weighting for eight pre-determined health subscales, and each of the subscales are scored separately using additive scaling. The health domain subscales are:

- Physical Functioning
- Role Physical

- Bodily Pain

- General Health

- Vitality

- Social Functioning

- Role Emotional

- Mental Health

In addition, a Physical Component Score (PCS) and a Mental Component Score (MCS) can be computed. These summary scores range from 0 to 100, with higher scores indicating better health functioning. The PCS and MCS are directly related to scores for the initial population involved in the Medical Outcomes Study, a group representative of the general US population, in which the standardised mean score is 50, and the standard deviation is 10. For this reason, countries, including Aotearoa New Zealand, have developed their own population norms and scoring coefficients, which have been estimated using national health survey data (Frieling et al., 2013).

Using the PCS of the SF-36 as our primary outcome measure had several other advantages.

Psychometric Properties

Since its inception, the SF-36 has been subjected to rigorous psychometric testing in multiple studies. All of the SF-36 subscales have demonstrated excellent internal consistency (Cronbach's alpha > 0.80) except Social Functioning (Cronbach's alpha = 0.73), which may be explained by there being fewer items (only two questions) on the Social Functioning subscale (Lyons, Perry, & Littlepage, 1994). Reliability testing in large populations of over 10,000 people have demonstrated similar results (Jenkinson, Wright, & Coulter, 1994).

The SF-36 has also been validated as an instrument in Australian people with stroke. Anderson and colleagues administered the Australian / New Zealand version of the SF-36 to 90 people at 1-year post-stroke (Anderson, Laubscher, & Burns, 1996). These scores were compared with scores obtained from the Barthel Index (BI), the 28-item General Health Questionnaire (GHQ-28), and the Adelaide Activities Profile (AAP), an instrument derived from the FAI to assess extended activities of daily living. The PCS changes correlated well with changes in the BI, and the MCS changes correlated well with changes in the GHQ-28. Important correlations were reported between scales and specific dimensions of quality of life such as living arrangements, financial situation and family life.

In this study, the Social Functioning subscale was again unable to adequately capture the extent of activities and community engagement of older people compared with the AAP, and supplementing the SF-36 with an additional instrument such as the AAP was recommended. Construct validity was also demonstrated as there were significant differences across the 8 subscales for patients with known health problems. Ceiling effects were reported for 4 of the subscales, but no floor effects exceeding 7% were reported for the SF-36. Scores for the Physical Functioning subscale were more uniformly distributed than scores in the Barthel Index, which suggested that the SF-36 had lower floor and ceiling effects than the Barthel Index.

We were unable to find published trials formally testing the responsiveness of the SF-36 specifically in stroke. However, in one study, the SF-12 (see Section 3.6.3, page 150) was administered to 558 patients at baseline and 12 months after stroke or TIA, and standardised response means (SRMs) were small for the PCS and moderate for the MCS. This study also showed that the responsiveness of the SF-12 was higher in patients with greater stroke severity (Müller-Nordhorn et al., 2005).

Through rigorous and ongoing testing and usage, the SF-36 has demonstrated strong and reproducible psychometric properties in multiple populations, including general populations, and populations with acute and chronic health conditions, as well as persons with stroke.

Generic Health Scale

We chose the SF-36 because it was important to us that quality of life was not restricted to or determined by factors that were specific to the stroke. Our priority was assessing a person's holistic wellbeing. An intervention was deemed useful in our eyes if it was able to affect the health of a whole person, not just a one or two aspects of a person's life. From a WHO-ICF perspective, we were interested in outcomes at the level of a person's ability to participate in society, rather than body function and impairments.

Broadly speaking, two types of quality of life scale exist in health research: condition-specific and generic scales. Recognising that the quality of life of a person with stroke may be affected by other comorbidities, we chose to use a generic health measure. An instrument such as the General Self-Efficacy Scale could have provided useful information about a person's perceived self-efficacy, but this scale was felt to be too broad. Scores correlated with emotion, optimism, and work satisfaction, and the scale is used primarily in education research by psychologists. At the opposite end, we chose to trade-off the detail that the Stroke Specific Quality of Life Scale might have captured to allow better understanding of overall health, rather than health purely related to stroke symptoms, impairments, and activity limitations.

Cost-effectiveness analysis

As a quality of life measure, the SF-36 scores are able to be quantified into health utility measures such as Quality Adjusted Life Years (QALYs) allowing comparison between different time points, countries and people. For TaCAS, this meant that if the present

study's results were positive, we would then be able to conduct an economic analysis showing cost-effectiveness in improving outcomes, compared with other interventions in other conditions.

Within a country, statisticians can also derive norms specific for the country's citizens, which can not only reflect differences in health status between countries, but also differences in perceptions of health and the meaning of health between cultures. This has been the case in Aotearoa New Zealand, and our scoring coefficients have been derived and published based on results from a national health survey (Frieling et al., 2013).

Those in charge of health funding would be able to use the results of the cost-effectiveness analysis to determine the potential value (QALYs) that could be gained for the population of people with stroke in Aotearoa New Zealand, if the Take Charge session was implemented. The cost-effectiveness analysis will be outside the scope of this thesis and its results will be published separately.

Prior use of SF-36 in MaPSS

The PCS was the primary outcome measure in the Māori and Pacific Stroke Study (MaPSS). Using the MaPSS results, we were able to calculate a sample size (n = 360) that would ensure TaCAS would be adequately powered to detect a meaningful difference in the PCS (see Section 3.9). This information was important for writing our research proposal and applying for funding from the Health Research Council of New Zealand (HRC).

The other advantage of using the PCS as our primary outcome was that it would allow meta-analysis of pooled patient data from both studies.

However, a key finding in MaPSS was that the Mental Component Summary (MCS) score was not sensitive to change. This was curious, because the Take Charge intervention was largely a psychological intervention more than it was a physical one. Reasons for why the MCS did not respond Take Charge – especially when the PCS showed a significant effect estimate between groups – are unclear. In fact, to our best knowledge, no interventional studies in stroke have explicitly used the MCS of the SF-36 as a primary outcome and observed change between treatment groups. It is possible that even though the subscales of the SF-36 are valid and consistent against other health measures, when summarised as the MCS the results lose their sensitivity. Therefore, we would not expect the Take Charge intervention to have any effect on the MCS in the TaCAS study.

Criticisms of the SF-36

The use of SF-36 in stroke research has been contentious at times. In 2002, Hobart and colleagues claimed that the 5 of the 8 SF-36 subscales had limited validity after testing the results of 177 people with mild to moderate stroke using scaling assumptions (Jeremy C Hobart, Williams, Moran, & Thompson, 2002). However, the SF-36's design meant that its psychometric evaluation as a scale was highly dependent upon the average levels of the patients being tested. Therefore, notable floor and ceiling effects would have appeared in this small cohort of people with lower than average health.

In response, de Haan argued that Hobart had provided insufficient evidence to question the reliability and validity of the SF-36 in stroke research in the face of a large body of evidence that the SF-36 was psychometrically sound (de Haan, 2002). However, de Haan did not support the use of the summary scores in current stroke research. He believed that the problem with the summary scores was caused by their scoring algorithm, which used negatively weighted subscale factor score coefficients. Other researchers also

advised against using the summary scores in stroke research until the developers statistically revised the current scoring methods (Taft, Karlsson, & Sullivan, 2001).

Despite these criticisms, in light of there not being any other psychometrically robust scoring systems available that had been widely used in stroke, and the fact that statistically and clinically significant differences in the PCS were noted in MaPSS, the PCS of the SF-36 remained the best available choice for our primary outcome variable.

3.6.3   The Short Form 12-item Questionnaire

The SF-12 was used in TaCAS at the baseline (V1) and V2 visits as an interview-type questionnaire. It was also used as an outcome measure in the self-reported questionnaire at six months. It was selected over the SF-36 primarily to reduce responder burden and increase participant retention.

The developers of the SF-36 derived a shorter version, the SF-12, which was made up of a selection of 12 questions from the SF-36 (John E Ware, Kosinski, & Keller, 1996). Its main advantage is its ability to reduce responder burden by being considerably shorter than the SF-36, while still capturing important health information. An improvement to the SF-12 meant that version 2 could also report the eight scale scores in addition to producing the PCS and MCS accurately and without substantial loss of information.

Standardised norm-based scoring meant that norms were comparable across the 8-scale profile, and for the PCS and MCS estimated from all the Short Form surveys. Although the PCS and MCS derived from the SF-36 and the SF-12 are not 100% exact, large population studies across multiple countries showed that correlation between the summary measures was very high, with the PCS ranging from 0.94 to 0.96 (Gandek et al., 1998). This high correlation occurred in the standard and country-specific scoring of the SF-36 or SF-12.

However, the developers acknowledged that using a shorter survey resulted in a trade-off in precision. Although the average scores for all the SF-12 domains closely mirrored those of the SF-36, the standard errors of measurement were nearly always larger for the SF-12 (John E Ware et al., 1996).

3.6.4   The Modified Rankin Scale

The modified Rankin Scale (mRS) is a rating scale of global outcomes that was developed for patients post-stroke (Rankin, 1957). At face value, its use is straightforward. It is a six-point, single item scale commonly used in stroke trials to assess the effects of an intervention on functional outcomes. Zero indicates complete independence with no symptoms, five means severe disability requiring full nursing cares, and six equates to being dead.

Although the mRS is one of the most commonly used outcome measures in stroke trials, there are several reasons why it is a problematic measure. First, the definitions of each category are too broad and poorly defined, which leaves the interpretation of each level open to the assessor. Inter-rater reliability is therefore somewhat low, especially in studies with larger sample sizes (Quinn, Dawson, Walters, & Lees, 2009). Also, the use of the term 'without assistance' is ambiguous. Whether 'assistance' refers to the use of assistive aids, devices, or environmental modifications, or whether it refers to assistance by another person or persons is not defined. The mandated mRS training programme available for purchase online specifies that use of assistive aids, such as a walking stick, can still be counted as independent mobility.

It has been noted, however, that modifications and compensatory techniques may allow the person with stroke to improve their performance in activities of daily living, but these may result in a higher (more disabled) grading on the mRS (New & Buchbinder,

151

2006). For example, a person with stroke who has a chairlift installed may require this for problems with balance, visual impairment, or proprioception while taking stairs in the home. The chairlift might increase their overall independence, but would lead to a score of 4 on the mRS.

Similarly, an otherwise independent person with stroke who has unilateral hand weakness may need assistance from another person with a specific task, such as putting on a bra. This person would also score 4 on mRS (moderately severe disability: requires some help with daily tasks, whether walking, dressing, toileting, or eating.)

The broadness of each level in the mRS also means that as a scale it is inherently insensitive to changes in disability (Dromerick, Edwards, & Diringer, 2003). Content validity of the mRS, that is, whether or not as a measurement it covers a representative sample of the domain it seeks to measure, is very difficult to assess because it mixes all three domains of impairment, activity limitation, and participation restriction in one scale. The same scale also combines objective and subjective items.

Furthermore, there is no clear consensus on how to best dichotomise the mRS, although dichotomised results are now commonly reported in stroke trials. New & Buchbinder found multiple methods had been used to dichotomise the mRS in several different trials (2006). There is genuine concern about arbitrary cut-offs being used to determine whether a trial is negative or positive. Some authors advocate for a 'favourable outcome' being defined as an improvement in grade within the mRS, rather than as an arbitrary cut-off at either mRS 0-1 or mRS 0-2 (P. Duncan et al., 2000).

Despite the above concerns, the mRS was included in TaCAS for several reasons.

First, we needed to include it in case some participants were unable to complete the full follow-ups, especially the Short Form questionnaires. Its ease and speed of collection made it ideal for collecting important, basic data about global function. At the very least we would be able to gather, by proxy, an mRS score and BI from the carers of participants who were unable to complete the Short Forms.

Second, because the use of the mRS is widespread in acute stroke studies, gathering mRS data from our study population would facilitate better understanding of our results among practitioners and physicians who might be less familiar with scales such as the SF-36.

Finally, in the Māori and Pacific Stroke study, by measuring the mRS the investigators were able to show that the Take Charge session was able to reduce dependence at 12 months (using an odds ratio of dichotomised mRS). It was vital for us to repeat this to see whether the finding held. To allow meta-analysis with the Māori and Pacific Stroke study data, we chose to retain the mRS in our statistical analysis dichotomised at 0-2 and 3-5. Acute stroke trials commonly dichotomise at this level to determine 'independence' versus 'dependence' (Buchan et al., 2000). We also included an analysis of the mRS as an ordinal variable at 6 and 12 months, to test whether there was any difference between treatment received and mRS at each time point.

3.6.5   The Barthel Index

The Barthel Index (BI) is a 10-item scale measuring disability which was developed in 1955 by Dr Florence Mahoney, and Dorothea Barthel, a physiotherapist. This scale was used as 'a simple index of independence to score the ability of a patient with a neuromuscular or musculoskeletal disorder to care for himself, and… to assess his improvement' (Mahoney & Barthel, 1965). Two items relate to mobility, and eight items

relate to personal care. Because it examines the ability of an individual to live within his/her immediate environment, the BI measures at the ICF level of activity limitation.

The initial BI was scaled from 0 – 100, but a modified version simplified the scoring to give results from 0 – 20 (D. T. Wade & Collin, 1988). In his book, Wade explained that scoring from 0 – 100 gave a false sense of '*great sensitivity, and it seems more honest to use a 0 – 20 score which can always be multiplied up if percentage scores seem better*' (D. Wade, 1992). Higher values indicate greater levels of independence at performing basic activities of daily living (ADL).

The main advantage of the BI is that it is simple to administer. Because it can rely on either personal report or objectively observed information collected during functional assessment, it is more convenient and cost-effective in longitudinal assessment, and its everyday use across a wide range of settings means most clinicians are familiar with how to interpret the results.

The BI has undergone vigorous psychometric testing in people with stroke and continues to be an essential outcome measure in stroke trials. Because of its longevity, the breadth of research about its psychometrics is enormous and impossible to cover entirely within this thesis.

The BI has excellent internal consistency when compared with the Functional Independent Measure (FIM) and the 30-item FIM and Functional Assessment Measure (FIM+FAM), with one study finding a Cronbach's alpha of 0.94 (J C Hobart et al., 2001). However, this is no surprise because the FIM was developed directly from the BI by Granger and colleagues, who were keen to address the issues of sensitivity and comprehensiveness in the BI (Keith, Granger, Hamilton, & Sherwin, 1987). Despite this, the BI also correlates well with clinical impression and motor loss after stroke.

The earliest study of the reliability of the BI was assessed by comparing self-report, asking a trained nurse who had cared for a patient within one shift, and two skilled observers within 72 hours of admission (Collin, Wade, Davies, & Horne, 1988). This study found that a difference of 4/20 points was likely to reflect a genuine difference, but a difference <4 could be due to inter-observer variability. Differences of ≥5 points were thought to almost always reflect real change. A subsequent meta-analysis found the inter-rater reliability of the BI in people with stroke to be excellent in eight out of ten studies (Duffy, Gajree, Langhorne, Stott, & Quinn, 2013).

Wood-Dauphinee and colleagues used the coefficient of variation (SD/mean) to show that the Barthel ADL index was the most sensitive measure for assessing morbidity after stroke out of six different stroke outcome measures (Wood-Dauphinee, Williams, & Shapiro, 2017). These measures included two clinical scales: a stroke severity scale; one motor scale: the Fugl-Meyer scale; and two functional scales: the Barthel Index, and the ADL and cognition subscales of the Level of Rehabilitation Scale.

By studying two groups of patients with sub-acute stroke and chronic stroke, Hsieh and colleagues were able to report a calculated minimal clinically important difference (MCID) for the BI. A mean BI change score of 1.85 was calculated to correspond best with patient self-reported ratings of minimally important change (Hsieh et al., 2007). This estimate of MCID applies only to improvement, as no individual in this study reported deterioration.

The BI is limited by its relative insensitivity, which is especially noticeable in its sizeable reported floor and ceiling effects. It seems to be more responsive to people with moderate to severe stroke but has a poorer response to changes in people with mild stroke (P W Duncan et al., 1997).

Like the modified Rankin scale, studies also commonly report dichotomised BI results. The reporting of dichotomised results is problematic because it compounds the insensitivity of the BI because of imprecision. Having larger categories makes it even more difficult for the scale to detect change.

However, some would argue that dichotomising the BI allows simplification and a better understanding of the results. For example, in the Copenhagen Stroke study, the severity of disability was determined by stratifying patients into pre-specified categories: 0-4 indicating very severe disability, 5-9 indicating severe disability, 10-14 indicating moderate disability, 15-19 indicating mild disability, and 20 being not disabled (Jørgensen et al., 1995). At all dichotomised levels, initial BI correlated well with BI at discharge from rehabilitation, with statistically significant differences between the dichotomised groups (see Figure 9, page 157). It would make sense that functional ability within the first week of stroke would better predict future functional ability than initial, focal neurological deficits. The investigators also showed that the BI at baseline was more reliable at determining prognosis than initial stroke severity, as determined by the Scandinavian Stroke Scale (Jørgensen et al., 1995). For this reason, the BI was used as an outcome measure in TaCAS and also as a measure of stroke severity.

Figure 9. Time course of recovery in relation to initial functional disability.

Reprinted from Archives of Physical Medicine and Rehabilitation, Vol 76, Jørgensen, HS; Nakayama, H; Raaschou, HO; Vive-Larsen, J; Støier, M; Olsen, TS. Outcome and time course of recovery in stroke. Part II: Time course of recovery. The Copenhagen Stroke Study, p 410. Copyright (1995), with permission from Elsevier.
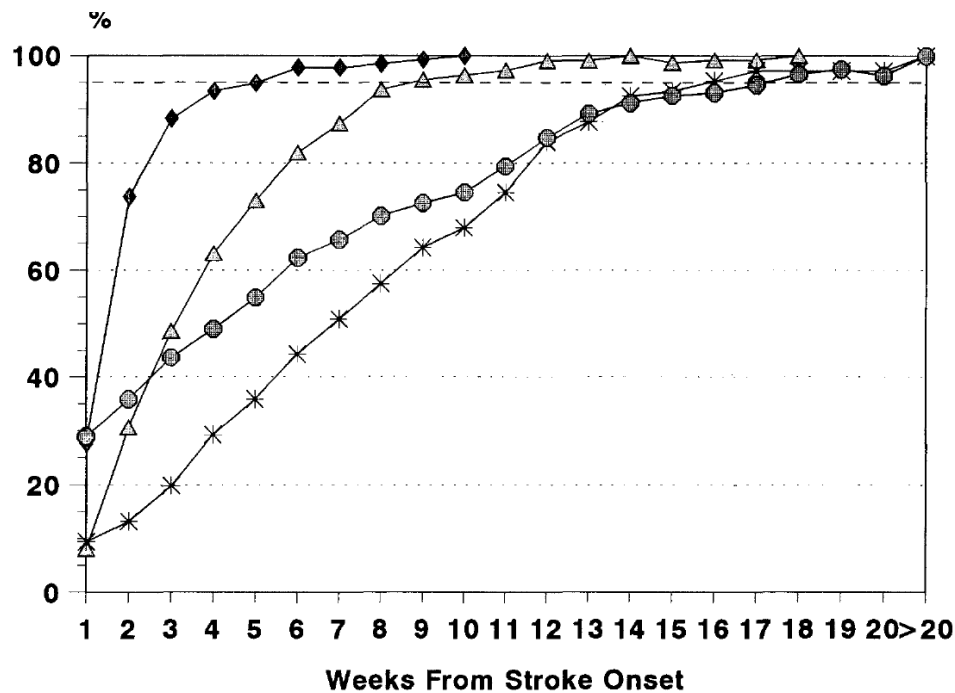
Fig 3—The time course of recovery in survivors shown as the cumulated rate of patients having reached their best ADL function in relation to initial functional disability. Rates are given,—; for patients with initial mild disability, ♦; for patients with initial moderate disability, ▲; for patients with initial severe disability, *; for patients with initial very severe disability, ●. The ANOVA test showed an overall difference in the time course of recovery between the groups, $p < 0.0001$. Further analyses showed that the time course of recovery differed significantly between patients with initially mild disability versus moderate disability, $p < 0.0001$, and between patients with moderate disability versus severe disability, $p < 0.0001$, and between patients with initially severe disability versus very severe disability, $p < 0.0006$.

To further support its use as a prognostic indicator, we sought evidence to narrow down the optimum assessment window of the BI. Kwakkel and colleagues showed that completing the BI early post-stroke showed good discriminative properties of the BI at six months (Kwakkel, Veerbeek, Harmeling-Van Der Wel, Van Wegen, & Kollen, 2011). To determine whether outcomes could be predicted early after stroke, the BI was measured at Day 2, Day 5 and Day 9 after stroke. Odds ratio, sensitivity, specificity, positive predictive value, and negative predictive value were calculated to predict a BI ≥19 at six months (signifying 'independence'). There was no significant difference

between the area under the curve of the receiver operating curves at Day 5 and Day 9 (z =1.416, p = 0.08).

Day 5 was determined as the earliest, most optimal day of assessment for accuracy. Completing a BI within 72 hours of stroke was not suitable for measuring disability as the score tended to be underestimated. A patient who was neurologically or medically unstable, or who was comatose due to early brain oedema in the first three days of stroke would automatically score a 0. The performance of patients who were bedridden in the early days after stroke was also difficult for observers to determine accurately.

In TaCAS, we used a measure of "Day 5 – 7 BI" as our prognostic marker of stroke severity. We dichotomised the scores in a fashion similar to that in the Copenhagen Stroke Study, except the scores for 'very severe disability' and 'severe disability' were grouped, and we removed the 'no disability' category, in recognition of the BI's ceiling effect. In TaCAS, 0 – 10 indicated severe disability, 11 – 14 indicated moderate disability, and 15 – 20 indicated mild disability.

There were a number of reasons why we chose to use the BI as our prognostic marker over the National Institute of Health Stroke Severity (NIHSS) scale, which is commonly used in acute stroke trials.

First, as mentioned previously, the BI is relatively easy to administer. Unlike the NIHSS and mRS, assessors do not require formal teaching on how to score the BI. Second, our focus from the outset was on the person as a whole, and measuring at the level of activity limitation would provide information that was more relevant to TaCAS than measuring at the level of impairment, which only covered a participant's degree of neurological deficits. Third, the NIHSS was impractical for use in TaCAS firstly, because the scale's use is neither routine nor widespread in hospitals around New Zealand, and secondly,

because the NIHSS is difficult to score retrospectively based on documentation and medical records.

For these reasons, and because of the extensive evidence supporting the BI's psychometric properties, it was chosen as our stroke severity prognostic indicator when measured at Day

5 – 7 after stroke, and as our six- and 12-month outcome measure of activity limitation.

3.6.6   The Frenchay Activities Index

The Frenchay Activities Index (FAI) was specifically developed to measure 'lifestyle' of people with stroke, with the hope that it would assist with determining rehabilitation goals (Holbrook & Skilbeck, 1983). As with the BI, Wade modified the original scoring system for simplicity from a summed score of 15 – 60 to a summed score of 0 – 45 (D T Wade, Legh-Smith, & Langton Hewer, 1985).

The FAI measures a person's level of engagement in extended activities of daily living, therefore, it measures at the ICF level of participation. It consists of 15 items asking how often a person has engaged in activities related to the home (meal preparation, doing the dishes, doing the laundry, housework), leisure (reading, hobbies), social activities (travelling, meeting other people), and gainful work in recent months. The items are scored based on the frequency of participation. The instrument has been validated for use in people with stroke and has shown good correlation with the Barthel Index (Schuling, de Haan, Limburg, & Groenier, 1993).

The main psychometric properties of reliability, validity, and responsiveness are generally adequate to excellent. It is simple to administer, takes approximately five minutes to complete, and can be administered in an interview format, with or without the patient's family present. The sum FAI score has excellent agreement between

159

patient and proxy, so the scale is inclusive of patients with cognitive or communication difficulties (Tooth, McKenna, & Smith, 2003). However, some disagreement has been observed at the item level between the proxy and patient responses. Tooth and colleagues also found that patients tended to score themselves as performing activities more frequently than proxy respondents (Tooth et al., 2003). Also, gender and age may influence FAI scores, because of traditional gender roles leading to women having a higher frequency of performing domestic chores than men, and men scoring higher in outdoor activities. Younger age has also been found to be associated with better scores on the FAI. On regression analysis, age was found to be significantly associated with FAI scores one year after stroke, such that each year increase in age reduced the FAI score by 0.57 points (Appelros, 2007).

Another limitation of the FAI is that in patients with chronic stroke, the smallest real difference is estimated to be quite large: a 6.7 point change score (Lu, Chen, Huang, & Hsieh, 2012). This is important to bear in mind when re-assessing individual patients to detect change.

In time, it may be that individual items of the FAI may need to be redefined to maintain relevance with changes in society. For the majority of participants in the TaCAS study, the descriptions of extended ADLs are appropriate. In TaCAS, the FAI was used as a measure of baseline participation, and as an outcome measure at six and 12 months.

3.6.7   The Patient Health Questionnaire – 2 (PHQ-2)

Because of the well-documented association between stroke and depression (Hackett & Pickles, 2014), it was important that we included a brief instrument to assess mood in our TaCAS participants. Although the SF-12 and SF-36 both have a mental component summary score (MCS), a low MCS would not be specific to depression. Likewise, the mood item in the EQ-5D refers to anxiety and depression. We included a specific

depression screen to supplement our existing mood questions because the presence of major depressive disorder could influence several outcomes. These outcomes included a person's chance of being on an anti-depressant, such as fluoxetine, and their overall quality of life and ability to participate in life actively.

The Patient Health Questionnaire – 2 (PHQ-2) was chosen as the most appropriate instrument. It comprises the first two questions of the PHQ-9, a tool that is commonly used in primary care to screen for major depression. The PHQ-2 asks about the frequency of the symptoms of depressed mood and anhedonia over the past two weeks, scoring each as 0 (not at all) to 3 (nearly every day).

The largest validation study for the PHQ-2 was conducted in 2642 patients enrolled in general practices in Auckland, New Zealand. Arroll and colleagues found that the sensitivity and specificity of the PHQ-2 for diagnosing major depression were 86% and 78% with a score of 2 or higher (Arroll et al., 2010). With a score of 3 or higher, the sensitivity decreased to 61%, but the specificity increased to 92%. These results are similar to those of the PHQ-9, allowing the PHQ-2 to be used as adequate screening for major depression. However, the tool has not been validated in people with stroke.

In TaCAS, it was important to maintain as much brevity as possible to reduce the chances of data loss or loss to follow-up. The choice of the PHQ-2 was an example of choosing a brief instrument at the expense of precision, at the same time aware that the SF-12 / SF-36 and EuroQOL EQ-5D-5L include items assessing mood, anxiety, and depression.

3.6.8   The EuroQOL EQ-5D-5L

In addition to the SF-36, we included the EuroQOL EQ-5D-5L (EQ5D) as a quality of life measurement to be used primarily as a health utilities index. We anticipated the need to

use health utility measures in the economic analysis of TaCAS, which had the aim of determining the cost-effectiveness of the Take Charge session intervention. The instrument was quick to administer, even though it meant some repetition of similar questions from other instruments.

The EQ5D is a generic instrument developed by a multi-country, multi-disciplinary team, and is used to value and describe health states. It was developed with the intention to promote the collection of a common data set to be used as a reference within large populations (such as countries), and as a comparison between populations. It is a self-administered questionnaire made up of two parts.

The first half contains a descriptive profile of health in five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each dimension is scored in five levels of severity: (1) no problems, (2) slight problems, (3) moderate problems, (4) severe problems, and (5) extreme problems or unable. The participant ascribes the statement they feel best represents their current state in each dimension. The choice results in a 1 digit number (from 1 to 5). The results are written as a five digit number that describes the person's health state, e.g. 12134.

The second part is a visual analogue scale from 0 – 100, on which the participant is asked to mark the score which best describes their current health.

The advantages of the EQ5D are a high response rate due to its simplicity and ease of completion usually within two to three minutes. It also provides information in three distinct forms: an individual patient profile of health in five domains, a population-weighted health utility or index, and an overall rating of perceived health (the visual acuity scale [VAS]). Furthermore, the 5L version has improved ceiling effects and discriminatory power of the tool compared to its 3L version (Janssen et al., 2013).

One of the limitations of the EQ-5D is that rate of missing data is associated with increasing age of the respondent. In a group of elderly acute care patients over 65 years of age, the ability to self-complete the EQ-5D was directly related to age and cognitive function ($p < 0.0001$) (Coast, Peters, Richards, & Gunnell, 1998). The same study also found that the probability of requiring an interviewer to administer the Eq-5D increased with age.

The EQ5D has adequate validity but is less useful as a serial assessment of individual patients. For this reason, it was not included in the baseline assessment in TaCAS. It was included in the six-month assessment not to be used as a comparator for change over time, but to reduce the chance of loss of data due to loss to follow-up or death before 12 months. The population-based value sets for the 5L version are not yet available for the New Zealand population, but cross-walk value sets based on the 3L are available to allow interpretation.

3.6.9   The Caregiver Strain Index

The Caregiver Strain Index (CSI) is a simple 13-item instrument used to measure the self-rated strain upon main caregivers of people with illness using items with dichotomous yes/no responses. It was first developed and validated in 1983, amongst a sample of spouses, family, friends, and neighbours, aged 22 to 83, who provided care to recently hospitalised hip surgery and heart disease patients aged 65 and over (Robinson, 1983). Its brevity and ease of administration have ensured its extensive use in research into the health of carers of people affected by many different conditions.

It has been validated for use in people with stroke. In a small study of the carers of Dutch people with stroke three years after stroke, Post and colleagues found that the CSI

showed good reproducibility (0.93, 95% CI 0.84 to 0.97) and moderate responsiveness (Post, Festen, van de Port, & Visser-Meily, 2007). Furthermore, construct validity showed adequate to excellent correlation against other caregiver burden scales, and no floor to ceiling effects (van Exel et al., 2004). Compared to these other scales, however, the CSI was neither too complicated nor too short and has been translated into several languages.

In MaPSS, the Take Charge intervention was associated with a lower (better) CSI score (–1.5 points, 95% CI –2.8 to –0.1, p = 0.034). The effect size was small but statistically significant. It was essential to include the CSI as an outcome measure in TaCAS, to see whether this effect could be replicated in a larger study. In MaPSS, caregivers self-identified or were identified by participants, and this would be replicated in TaCAS. Caregivers would be taken to consent to participate if they willingly completed the CSI on paper or in person. They would not, therefore, be separately consented.

3.6.10 The Patient Activation Measure (PAM)

The Patient Activation Measure (PAM) was developed in the US in response to growing health care costs (J. H. Hibbard, Stockard, Mahoney, & Tusler, 2004). The developers' aims were two-fold: to reduce costs, especially when caring for people with chronic diseases, and to improve outcomes. The purpose of the PAM was to determine a patient's level of "activation" or their ability to manage their own health needs. Two elements contributed to the idea that activation was significant. The first notion was that with comparative information and financial incentives, patients would make prudent health care choices if they were more activated. The second element was the Chronic Illness Care model which emphasised the importance of patient-oriented care, and accordingly, the developers of the PAM felt that patients and their families needed to be motivated and skilled to be part of the care team.

The developers used a national expert panel and patient focus groups to define activation and its domains. The initial version was tested in a large population sample of 1,515 people, and resulted in the determination of four stages of activation (J. H. Hibbard et al., 2004):

Stage 1:   Believing the patient role is important

Stage 2:   Having the confidence and knowledge necessary to take action

Stage 3:   Actually taking action to maintain and improve one's health

Stage 4:   Staying the course even under stress

The initial 22-item instrument was tested, and showed reliability and construct validity when measured against the eight-item Short Form (SF-8). The developers further condensed the PAM into thirteen statements, which make up the final instrument. Available responses are in a probabilistic, Likert format, i.e. from "Disagree strongly to Agree strongly". The responses are converted using licensed software from the developers to give a final score out of 100, and a corresponding categorisation into one of the four stages of activation (J. H. Hibbard, Mahoney, Stockard, & Tusler, 2005).

Since its inception in 2004, the PAM-13 has been translated into multiple languages, and tested, validated, and used as a measurement tool in multiple countries and diverse patient groups (Insignia Health, 2018). National health services have adopted patient activation as a determinant of health outcomes, health service usage, and measure for the effectiveness of interventions (J. Hibbard & Gilburt, 2014). Use of the PAM-13 is encouraged alongside a tailored coaching approach, so that a clinician is aware of the type and amount of support that is likely to be helpful to the patient, depending upon their level of activation.

We chose to include the PAM as an outcome assessment because it measures concepts relevant to the Take Charge session such as self-efficacy, and we suspected that activation itself might also be a mechanism through which the Take Charge session asserted its action. Furthermore, a randomised controlled trial using the Chronic Disease Self-Management Programme (CDSMP) as an intervention showed that activation levels changed over time in both groups and modelling was used to predict whether a change in activation led to a change in behaviour. The results were suggestive but not statistically significant (J. H. Hibbard, Mahoney, Stock, & Tusler, 2007). We sought to determine whether any improvements in outcome due to the Take Charge session were associated with an increase in patient activation. The PAM's well-established psychometrics were favourable, although we were unable to identify any studies in which the instrument had been used in persons with stroke. Including the PAM as an outcome measure, therefore, allowed us to gather PAM data in a moderately large sample of people with stroke.

3.6.11 A measure of Autonomy Mastery Purpose & Connectedness (AMP-C)

The AMP-C was a brief measure developed by the research team as a means of exploring the important tenets of self-determination theory (SDT), a framework of human motivation and personality developed by Deci and Ryan. The components of the theory and how they relate to psychology in rehabilitation are detailed in Section 2.6.2, page 112.

Because SDT informed a considerable part of the formalised version of the Take Charge session, it made sense to measure the extent of autonomy, mastery, purpose, and connectedness that participants felt early after stroke at the time of randomisation, and at each point of follow-up.

The instrument we developed was given the acronym AMP-C for two reasons. Firstly, because the former three elements were intrinsic and modifiable by a person's psychology while the latter – connectedness – could be a function of other factors, such as social isolation. The second reason was because the definition of '*to amp something/somebody up*' was '*to increase strength or excitement*', which fitted well with the psychological needs of motivation ("Amp up definition and meaning | Collins English Dictionary," 2018).

We hypothesised that there might be an interaction between receiving the Take Charge session, the participant's AMP-C score, and the primary outcome of health-related quality of life. The only way to assess this was to develop a quick, rudimentary measure that captured the four elements, but which was not validated and unlikely to be very sensitive. Participants were therefore asked to report their level of agreement (from 'strongly agree, agree, disagree, and strongly disagree') with the following statements:

- My life has a clear sense of purpose.
- I feel in control of my life.
- I have the skills to make the most of my life.
- I feel connected to the important people in my life.

The inclusion of this instrument was very much experimental as we were not sure whether we could gain useful information from it. Any results gained from this instrument must, therefore, be interpreted with caution.

3.6.12   Other outcomes

Data about medications were gathered directly from participants at six and 12 months. The blinded outcomes assessor often reviewed tablets themselves at the 12 month home visit for completeness. Because one of the principal investigators had an interest in

adherence to secondary prevention, the Medication Adherence Questionnaire (MAQ) was added to the 12-month assessment as a self-reported medications adherence measure to see whether the Take Charge session affected adherence to secondary prevention (Lavsa, Holzworth, & Ansani, 2011). It is the most widely used medication adherence scale for research, and, being made up of four items, is the quickest to administer and score. One of its apparent advantages is the closed question format with "yes-saying" bias which allows disclosures for non-adherence (Tan, Patel, & Chang, 2014).

The research clinicians and blinded outcomes assessor measured blood pressure using an electronic blood pressure machine. Heart rate and rhythm were recorded manually. Initial height was recorded by the research clinicians using a tape measure, and electronic scales measured weight. No attempt was made to calibrate the machines at each centre, but all machines were of the same brand and issued from the Medical Research Institute (MRINZ).

Unexpected findings such as irregular heart rhythm in the setting of no previous documented or awareness of atrial fibrillation, malignant hypertension, or hypotension, were discussed with the participant and the local site investigator and telephoned through to the participant's general practitioner (GP). Similarly, concerns about medications (such as taking two blood pressure medications of the same class) were raised with the GP after the visit.

The local research clinicians gathered adverse event data. For completeness, serious adverse events were gathered from participants at 12 months and from reviewing local medical records. The blinded outcomes assessor gathered data about the index stroke (type of stroke, length of stay etc.) by reviewing local medical records. Work and income

data, to be used for the economic analysis, were gathered from participants by self-report.

3.7   The timing of assessments / 12-month visit

We allowed a window of ±14 days for the 6-month follow-up. Paper versions of the 6-month follow-up were posted approximately three weeks before the date indicating six months from the date of stroke. A paid, self-addressed envelope was provided with the posted questionnaires to facilitate their return. We sent the e-mail link to the electronic 6-month questionnaire 14 days before the date indicating six months from the date of stroke. Automatic reminders were sent weekly to the email addresses of those who requested the electronic questionnaire. Alerts would be sent to the blinded outcomes assessor if responses were not forthcoming so that these could be followed-up by telephone. Similarly, phone calls were made to participants to ensure they had received the questionnaire in the post and to provide assistance with completing the questionnaire if this was requested. Incomplete or inconsistent responses were checked by the blinded outcomes assessor, who would telephone the participant for clarification.

Because the 12-month assessments occurred during a face-to-face visit at the participant's home, a wider window for completing follow-up was allowed. Greater flexibility was needed for scheduling visits to occur in a specific location within a limited timeframe. 12-month visits were therefore scheduled between -28 days to +42 days from the 12-month anniversary of the date of stroke. Given the awareness about the time course of recovery of stroke, we thought that this window would have minimal impact on the outcome results. Assessing someone at just over 11 months after stroke would likely yield very similar results to an assessment of the same individual at just under 13.5 months after stroke. However, this wide window allowed unsuitable, missed, or forgotten appointments to be rescheduled to a date when the blinded outcomes

assessor would be available to travel back to the centre. This flexibility allowed a more comprehensive degree of follow-up. Table 6 summarises the main instruments and when they were administered.

Table 6. Schedule of assessments

Time point	Acute stroke	Randomisation (baseline 2-16 weeks after stroke)	6 months after acute stroke	12 months after acute stroke
Method	Retrospective casenote review	Face-to-face	Postal or electronic questionnaire	Face-to-face
Assessment name				
BI	X	X	X	X
Demographic information		X		
Medications		X		
FAI		X	X	X
mRS		X	X	X
SF-12 PCS		X	X	
SF-36 PCS				X
Risk factor assessment		X		
CSI			X	X
EuroQol EQ-5D			X	X
Admission to hospital			X	X[1]
Recurrent stroke			X	X[1]

[1]Checked by casenote review. BI = Barthel Index; FAI = Frenchay Activities Index; mRS = modified Rankin scale; SF-12 PCS = Physical Component Summary score of the Short Form 12; SF-36 PCS = Physical Component Summary score of the Short Form 36; CSI = Caregiver Strain Index; EuroQol EQ-5D = European Quality of Life group scale 5 Dimensions

3.8   Data collection and study management

Study data were collected and managed using REDCap electronic data capture tools hosted at the Medical Research Institute of New Zealand (Harris, Taylor, & Thielke, 2009). REDCap (Research Electronic Data Capture) is a secure, web-based application designed to support data capture for research studies, providing: 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources (Harris et al., 2009).

The baseline data were collected on paper forms by research clinicians at the initial home visits. These forms were scanned and sent to the data management team based at MRINZ for entry into REDCap. This database was designed to maintain complete blinding of the outcomes assessor. The data management team at MRINZ performed double data entry of the baseline visit data, which were reconciled at the closure of the study by a medical student.

Participants who completed the 6-month questionnaire online entered their data directly onto the REDCap database. The blinded outcomes assessor manually entered the 6-month data obtained by telephone or posted questionnaire. The blinded outcomes assessor also entered the 12-month data onto the database using an electronic tablet at the final home visit. This web-based data management system allowed allocation concealment, locking of completed entries and ad hoc consistency checks to be performed by study monitors.

The Take Charge session had no known harms associated with it. We planned to report the following serious adverse events (SAEs): death, life-threatening event, permanently

disabling or incapacitating event, hospitalisation and any significant medical event considered serious by the study investigator. All SAEs were reported to the New Zealand Central Health and Disability Ethics Committee of New Zealand (HDEC) in accordance with current guidelines, as well as to the MRINZ within 24 hours of the study investigators becoming aware of the event. Adverse event data were collected at each follow-up and during the study period if the participant or their next-of-kin notified the research team. No interim analysis, for either effectiveness or harm, was planned prior to completion of the study. There were no specific plans for independent auditing of this study; however, MRINZ research staff and the online database ensured a complete audit trail was available for external auditing, in the event this was required.

3.9   Statistical analysis

In MaPSS, the root mean square error for the PCS was 10.8. Using an estimated clinically significant difference as half a standard deviation (SD = 10, therefore 5), we calculated that a total sample size of 360, 120 in each of three arms, had 90% power to detect a difference of 5 points on the PCS. With provision for 10% drop out, we planned to recruit 400 participants.

All outcomes were analysed as intention-to-treat. The statistician who completed the analysis was not blinded to the active and control groups. For the primary outcome variable, the difference in mean PCS (between Take Charge groups and control and between high-dose Take Charge and low-dose Take charge) was by analysis of variance (ANOVA).

Secondary analyses included the following:

Using ANCOVA,

- the SF-36 PCS with adjustments for Barthel Index 5 -7 days after stroke, SF-12 PCS at baseline, age, sex, and whether living alone;
- to treat the amount of TCS (zero, one, or two sessions) as a dose variable;
- dichotomising SF-36 PCS at its median value (and using logistic regression for the probability of above or below the median); and
- categorising SF-36 PCS by quintiles (and using ordinal regression for the probability of a better score).

Pre-specified subgroups using an interaction analysis in general linear models were: age above or below 75 years, use of fluoxetine at baseline, presence of a significant communication problem, presence of a significant cognitive problem, gender, whether living alone, presence of a support person, ischaemic compared to haemorrhagic stroke, receipt of thrombolysis, receipt of thrombectomy, treatment in a tertiary centre, recruitment site, Day 5 – 7 Barthel Index categorised as Mild, Moderate, or Severe disability, and the slope relationship with AMP-C sum as a regression analysis.

The following variables were analysed by a general linear model (ANOVA): SF12-PCS after six months, Barthel Index after six and 12 months, Frenchay Activity Index after six and 12 months, EuroQol VAS, Carer Strain Index, AMP sum after six and 12 months; and AMPC sum after six and 12 months.

The following variables were analysed by ordinal regression: modified Rankin Scale after six and 12 months, PHQ-2 after six and 12 months, Patient Activation Measure after six and 12 months, Patient Activation Measure Level after six and 12 months; and the EuroQol Activity, Anxiety, Mobility, Pain, and Self-care dimensions.

The following variables were analysed by logistic regression: modified Rankin Scale dichotomised as 0-2 or 3-5 after six and 12 months; modified Rankin Scale dichotomised as 0-2 or 3-5 and death, after six and 12 months; Rehabilitation contact after six and 12 months; Death after six and 12 months; at least one readmission after 12 months, at least one recurrent stroke after 12 months; and a Medical Adherence Questionnaire score of zero after 12 months.

The pre-specified comparisons were between combined TCS 2 and TCS 1 with control; and between TCS 2 and TCS 1.

The individual participant meta-analysis of TaCAS and MaPSS was also performed. The treatment groups were 'TCS 1 + TCS 2' vs. control in the TaCAS trial and 'any treatment containing TCS' vs. 'any treatment that did not contain TCS' in the MaPSS study.

A general linear model (ANOVA) was used to evaluate the continuous outcome variables. The modelling strategy was test for an interaction between randomised group (as outlined above) and the study source, and if this was not statistically significant (P < 0.05) to estimate the "pooled TCS minus control" and "MaPSS minus TCS" differences as main effects. If a statistically significant interaction was found, then the model was used to estimate the effect of TCS minus control within each study.

Ordinal regression was used to model mRS as an ordinal variable where the odds ratio for association was such that a value greater than 1 implied a lower (better) mRS score. Logistic regression was used for mRS dichotomised as <3 or not. The interaction term was also tested for both these analyses with main effects only shown if this term was not statistically significant.

The data analysis for this study was generated using SAS software. Copyright 2002 – 2012. SAS Institute Inc. SAS and all other SAS Institute Inc. product or service names are registered trademarks or trademarks of SAS Institute Inc., Cary, NC, USA.

3.10   Ethics and funding

TaCAS was conducted in compliance with relevant New Zealand legislation including the Health Information Privacy Code, the Health and Disability Code and the New Zealand Bill of Rights Act. Ethics approval was provided by the HDEC, reference 15/CEN/115 and at the research office at each local site. Protocol amendments were first approved by the HDEC and then by local ethics committees before implementation.

The research clinicians obtained informed consent from the participants after the latter demonstrated understanding of what being in the study involved. The participant 'making a mark' on the consent form was accepted, but proxy consent by a surrogate was not. To maintain confidentiality, participant information was kept in the locked, central data office at MRINZ as well as at each local site in locked offices. The online database was password-protected and located on an encrypted server belonging to REDCap (Harris et al., 2009). Source data from TaCAS will be kept in secure premises for 15 years after completion of the study after which they will be destroyed.

The day-to-day management of the trial was undertaken by a management committee comprised of the principal investigator, Dr Harry McNaughton, the study coordinator and blinded outcomes assessor (myself), project manager, Tanya Baker, and a team of researchers based at MRINZ (see section 3.11 page 177 for further information about the study team). Dr McNaughton, our statistician, Dr Mark Weatherall, and I had access to the final trial dataset. The TaCAS Study Group met on an as-required basis and regular updates were communicated by newsletters and email. The majority of members met

regularly for national stroke and rehabilitation working groups, study days and conferences where progress and issues with the trial were informally discussed. Neither the principal investigator nor site investigators had competing interests.

All members of the TaCAS Study Group will contribute to, and be acknowledged in, the primary trial manuscript (which is currently submitted for publication). The HRC funding will be acknowledged in all publications. Results will also be presented at national and international stroke meetings, including the National Stroke Rehabilitation Working Group and National Stroke Clinical Working Group meetings. Participants who indicated their desire to receive the results of the study will have these sent to them once the study is published.

3.11   The study team and my role in the study

In the first six months of the study, my roles were as a study coordinator based at MRINZ.   I designed the REDCap database (Harris et al., 2009), incorporating the formats of the source document worksheets, the electronic version of the 6-month questionnaire and the 12-month questionnaire. I assisted with screening patients at Capital and Coast DHB and arranging the RC visits with potential participants by telephone. I also supported the RCs at external sites with advice and updates on recruitment numbers. We attempted to initiate two other external sites but were unsuccessful due to internal funding issues within these DHBs.

As the 6-month questionnaires began returning, I took on my other role as the masked outcomes assessor, by following up missing responses and completing the questionnaire

with participants by telephone. Approximately one year after trial commencement, I began the 12-month home visits to the participants. I scheduled each person's appointment, made my travel arrangements, and sent reminder text messages or e-mails a week in advance. The ten-week window in which participants were able to be seen allowed flexibility for a postponement when necessary. While visiting each DHB, I also visited the medical records department to gather data relevant to each participant's stroke admission and past medical history. This way I was able to track serious adverse events and readmissions.

I was assisted in my role by numerous support staff.

Joanna Read, the administrator at MRINZ, fielded phone calls from participants and passed information on to me, which ensured a constant line of communication while I was away on visits. She posted all of my visit appointment letters and followed-up with participants who had not responded within a given time. She was my first contact when the occasional, unexpected mishap arose.

Judith Riley, one of the RCs who remained with the study from beginning to end, was careful to maintain my blinding while providing advice and support about travelling and meeting participants. Her depth of experience in undertaking the Take Charge session shaped the advice we gave other RCs.

Kathryn Fernando, another RC from MRINZ, undertook face-to-face interviews which informed the qualitative sub-study of TaCAS. The aim of the qualitative study was to explore the factors perceived by participants to be important to their recovery, and how the Take Charge session may have exerted its effect. Kathryn and I coded and analysed the data from her interviews, and decided that we had reached data saturation after nine

interviews. This study is a current work in progress and is not included within this thesis.

Tony Mallon, research assistant at MRINZ, monitored the source data forms and communicated with all external site RCs. Judith and Tony did double data entry for the V1 and V2 source data. After completion of the study, Tony monitored all of the 6-month and 12-month questionnaire data.

Tanya Baker, studies manager at MRINZ, assisted with submitting the ethics applications and communications with the HDEC. She liaised with the research managers and PIs of external sites to maintain contractual agreements. She provided ICH-GCP training at the RC training day.

James Berry, medical student, took over following up the 6-month questionnaires after my visits began. He was also masked to treatment allocation during this time. After completion of the study, James used REDCap and source data to reconcile all the data that had been double-entered (from V1 and V2) (Harris et al., 2009).

Nick Shortt and Allie Eathorne, both research assistants at MRINZ, assisted with any REDCap database issues (Harris et al., 2009).

Professor Mark Weatherall, statistician, undertook the statistical analysis as outlined in the protocol and the ANZCTR trial registration. SAS version 9.4 was used. He produced a statistical report and assisted in using statistical methodology to determine the minimal clinically important difference (MCID) of the SF-36 PCS in persons with stroke.

My supervisor, Dr Harry McNaughton, designed the TCS booklet, training manual, and trained the RCs at each site. He advised and supported me when this was required, but

maintained a distance and gave me full independence in running the study. His advice regarding the thesis-writing process has been indispensable.

Table 7 details the seven recruitment centres, their respective staff members, and the professional backgrounds of the research clinicians. Three research clinicians were responsible for two sites, Capital and Coast and Hutt Valley DHBs.

Table 7. TaCAS recruitment sites and staff

Recruiting DHB	Location	Principal Investigator	Research Clinicians (RCs)	Professional background of RCs
Capital and Coast	Wellington	Dr Harry McNaughton	Judith Riley Anna Hunt Kathryn Fernando	Research nurse Research nurse Community nurse
Hutt Valley	Hutt Valley	Dr Tom Thomson		
Canterbury	Christchurch	Dr Carl Hanger	Deborah Allen Haley Evans	Stroke nurse Physiotherapist
Auckland	Auckland	Anna McRae	Lauren Lucas Nicole Nancarrow	Physiotherapist
Counties Manukau	Middlemore	Dr Geoff Green	Amanda Retter	Research nurse
Hawkes Bay	Hawkes Bay	Dr John Gommans	Eryn Kyle-Foulds	Rehabilitation unit nurse
MidCentral	Palmerston North	Dr Anna Ranta	Rebekah Higgs	Physiotherapist

4 Results

We performed a prospective, observer-blinded, multi-centre, randomised controlled trial of the Take Charge session (TCS), a novel, person-centred intervention, in 400 non-Māori, non-Pacific people with stroke in Aotearoa New Zealand. The TaCAS study was performed to answer the question of whether this novel intervention could improve patient outcomes in community stroke. This chapter will present the results in the order of enrolment, follow-up, baseline characteristics, primary outcome, secondary outcomes, and subgroup analyses. This thesis will not include results of the economic analysis as this is currently a work in progress. The cost-effectiveness analysis of the Take Charge session will be reported in a separate paper.

In this chapter, continuous and ordinal variables are summarised by mean and standard deviation, median and inter-quartile range, and minimum to maximum. Categorical variables are summarised by counts and proportions. In box plots, the symbol is the mean; the horizontal lines are 25th, 50th (median) and 75th percentiles, and the whiskers extend from the minimum to maximum values.

Patients were recruited from Capital and Coast (39.25%), Canterbury (16.25%), Hutt Valley (14.75%), Counties Manukau (11%), and MidCentral (9.25%), Auckland (6.75%), and Hawkes Bay (2.75%) district health boards (DHBs). Capital and Coast and Hutt Valley DHBs are geographically adjacent and were managed by the same three RCs. Participants from these two DHBs made up 54% of the participants in the study.

Table 8 shows an even spread of participants distributed by randomisation.

4.1   Enrolment

Recruitment began in October 2016 and ended in August 2017, with 400 participants being randomised to either control or one of the two treatment groups (TCS 1 or TCS 2). 130 participants were randomised to control, 132 participants were randomised to one TCS, and 138 participants were randomised to receiving two TCS.

Without a nationwide stroke register, it was impossible to determine the number of patients with stroke who were admitted to hospitals residing within our screening DHBs. It was, therefore, also difficult to estimate the proportion of patients with stroke who were potentially eligible to participate in TaCAS out of the number of patients who were screened. The keeping of screening logs was variable between each DHB, and this was identified as being potentially difficult during the training and set-up of each centre. Logistic problems arose because patients tended to be screened by the inpatient stroke team or stroke nurse, and if the patient was deemed eligible and showed interest in participating, their details were passed on to the research clinician, who usually worked in the outpatient setting. Within the largest recruiting DHB, Capital and Coast, the three research clinicians screened in the stroke ward on alternate days.

Table 8. Randomisation of participants at each site

Recruiting DHB	Participants N = 400 n (%)	Control N = 130 n (%)	TCS 1 N = 132 n (%)	TCS 2 N = 138 n (%)
Capital and Coast	157 (39.3)	52 (40.0)	51 (38.6)	54 (39.1)
Hutt Valley	59 (14.8)	20 (15.4)	19 (14.4)	20 (14.5)
Canterbury	65 (16.3)	23 (17.7)	21 (15.9)	21 (15.2)
Auckland	27 (6.8)	8 (6.2)	10 (7.6)	9 (6.5)
Counties Manukau	44 (11)	14 (10.8)	15 (11.4)	15 (10.9)
Hawkes Bay	11 (2.8)	2 (1.5)	4 (3.0)	5 (3.6)
MidCentral	37 (9.3)	11 (8.5)	15 (11.4)	15 (10.9)

However, some information could be gained from the screenings logs kept at each site. *Table 9* shows the recorded number of participants who were excluded or declined participation. Note should be made that Canterbury DHB submitted their screening log only for the first 12 months of the 24 months of active recruitment, so an estimate is presented by multiplying their total by two.

The main reasons for exclusion were Māori and Pacific ethnicity (26.5%), fully recovered by the time of randomisation (16.2%), diagnosis not stroke (15.8%), and discharged to institutional care (14.1%). 12% were unable to consent or required an interpreter for English. The numbers of those who were excluded or who declined to participate are shown in Table *10*.

Table 9. Number of people excluded or declined from participation at each site

Site	Number of participants excluded or declined
Capital and Coast	804
Hutt Valley	251
Canterbury	208[1]
Auckland	437
Counties Manukau	789
Hawkes Bay	131
MidCentral	66
Total	2686

[1] Estimated by multiplying number of participants excluded after 12 months by two

4.1.1   Time taken for visits

Using recorded information from 15 visits and recollection from our research clinicians, we estimated the time it took for the baseline visit to be a mean (SD) of 120 (31) minutes, including consent procedures, randomisation, baseline assessments and the TCS intervention. Consent, randomisation, and baseline assessments were estimated to take between 60 to 80 minutes, and the TCS itself took a mean (SD) of 38 (6) minutes. The second visit (TCS 2) was estimated to be a mean (SD) of 66 (12) minutes.

Table 10. Numbers of participants excluded prior to randomisation and reasons for exclusion

Reason for exclusion		Totals
Did not meet inclusion criteria		2255
Ethnicity	598	
Fully recovered	366	
Not stroke diagnosis	357	
Institutional care	318	
Unable to consent	141	
Required interpreter	139	
Life expectancy < 12m	131	
Pre-stroke modified Rankin Score > 2	40	
Outside 16 week window	31	
Lives in different health district not in study	70	
Non-New Zealand resident	64	
Declined to participate		373
Declined	336	
Lives too far away	37	
Other		58
Discharged prior to verbal consent for contact	6	
Unable to contact	26	
Involved in another study	26	
Total excluded		2686

4.2   Follow-up

At the time of trial completion, participants had been followed for a median of 10 months (range, 1 to 13; interquartile range 9 to 11). Two of the 400 recruited participants (0.5%) were unable to be followed to death or final 12-month community visit. One of these participants was withdrawn immediately after randomisation due to safety concerns for the RC. This participant did not receive the baseline assessment or intervention. The other participant did not respond to the 6-month follow-up, and withdrew from the study before the 12-month visit. Using electronic health records we were able to determine that both subjects were alive at 12 months after stroke.

Where possible, missing 6-month and 12-month data were obtained over the telephone within the specified follow-up window. The lower rates of 6-month follow-up are primarily due to the voluntary nature of completing a questionnaire and returning it by post. To improve data collection, we introduced an electronic version of the questionnaire that the participant was able to access via an e-mail link. 75 surveys were completed with this method, and one electronic survey was used to gather 12-month data from a participant who had moved overseas. Furthermore, the masked outcomes assessor telephoned participants and offered to complete the 6-month questionnaire over the telephone. If this was declined, the mRS and BI were requested and recorded. As a result, the follow-up at 12 months in person was higher than the 6-month follow-up (Table 11). The enrolment, randomisation and follow-up of participants is further depicted in a CONSORT diagram in Figure 10.

Table 11. Subjects completing assessments at each time point

Assessment	Number completed / possible subjects enrolled and alive at each time point (%)
Initial baseline	400 (100%)
6 month postal	271 (68.8%)
6 month electronic	75 (19.0%)
6 month phone (mRS and BI only)	24 (6.1%)
Total followed-up at 6 months	370 (93.9%)
12 month home visit	380 (97.9%)
12 month phone	7 (1.8%)
12 month electronic	1 (0.26%)
Total followed-up at 12 months	388 (99.5%)

Figure 10. Enrolment, Randomisation, Treatment, and Follow-up

```
                    ┌──────────────────────────────────────────┐
                    │  3086 patients were assessed for eligibility │
                    └──────────────────────────────────────────┘
                                      │
                                      │──────────────────┐
                                      │                  ▼
                                      │      ┌────────────────────────────────────┐
                                      │      │ 2686  excluded                     │
                                      │      │ 2255  did not meet inclusion criteria │
                                      │      │ 373   declined to participate      │
                                      │      │ 58    other (not contactable)      │
                                      ▼      └────────────────────────────────────┘
                          ┌──────────────────┐
                          │  400 underwent    │
                          │  randomisation    │
                          └──────────────────┘
```

130 were assigned to control	132 were assigned to TCS 1	138 were assigned to TCS 2

| | 1 withdrew consent after randomisation | |

130 received control	131 received one TC	138 received one TC

| | | 3 declined second TC
2 died |

| | | 133 received two TC |

| 2 died | 1 withdrew consent
4 died | |

| 9 did not return 6m questionnaire | 5 did not return 6m questionnaire | 6 did not return 6m questionnaire |

119 completed 6-month follow-up	121 completed 6-month follow-up	130 completed 6-month follow-up

| | | 2 died |

128 completed 12-month follow-up	126 completed 12-month follow-up	134 completed 12-month follow-up

| 3 did not complete SF-36 due to cognitive impairment | 3 did not complete SF-36
1 declined
2 too unwell | 1 did not complete SF-36 due to cognitive impairment |

125 included in primary analysis	123 included in primary analysis	133 included in primary analysis

189

4.3   Baseline characteristics

This chapter presents the baseline characteristic data, including demographics, stroke data, and rehabilitation measures, such as level of function.

Data are presented from the three randomised groups to show comparability and to illustrate that groups were well-matched at baseline. However, these results need to be interpreted with caution. In general, it is poor practice to compare baseline results in a randomised controlled trial for a number of reasons: it inflates Type I error for the study as a whole, the scientifically important difference between baseline variables is uncertain, and the study was not powered to detect scientifically meaningful differences in baseline variables.

However, it was important to ensure that our primary outcome results would not be confounded by chance variability of variables between groups. We, therefore, pre-specified these important baseline co-variates which might account for variance in the primary outcome – age, gender, stroke severity, baseline SF-12 PCS, and whether the patient was living alone, and adjusted for these in a sensitivity analysis.

4.3.1   Demographics

Participants were representative of the New Zealand stroke population in all demographic characteristics except ethnicity (Feigin et al., 2014). There were no significant between-group differences at baseline. Mean time from stroke to randomisation was 45 days (sd 26, range 4 to 125). Table 12 on page 192 summarises the baseline demographic data.

Age and gender

The mean age of the patients was 72 years (sd 12.5, range 26 to 95). 54% of subjects were aged less than 65 years. There was a slight preponderance of men (58.5%). 34% of patients were living alone at trial entry.

Ethnicity

96.5% of participants self-identified with European ethnicity; 71.8% of participants identified as NZ European/Pākeha, and 24.8% as Other European. The Ministry of Health definitions of ethnicity data were used. Therefore, Other European included ethnicities such as Greek, Dutch, Australian, English, and Scottish. Of the ethnic minorities, five participants (1.25%) were Indian, two (0.5%) were South African, two (0.5%) were Filipino, and one (0.25%) was Chinese.

Table 12. Baseline characteristics – demographic data

Characteristic	Control N = 130	TCS 1 N = 132	TCS 2 N = 138
Age – years	73.0±12.2	71.4±12.6	71.7±12.6
Male sex – no. (%)	75 (57.7)	74 (56.1)	85 (61.6)
Ethnicity – no. (%)			
NZ European	97 (74.6)	92 (69.7)	98 (71.0)
Other European	27 (20.8)	35 (26.5)	37 (26.8)
Asian	4 (3.1)	4 (3.0)	1 (0.7)
African	1 (0.8)	1 (0.8)	2 (1.5)
Hispanic	1 (0.8)	0 (0)	0 (0)

4.3.2 Stroke data

Stroke severity

Stroke severity as determined by Day 5-7 BI score was mild to moderate, and well-matched in all groups. The mean (±SD) BI was 14.7 (±5.7) in the control group, 15.5 (±5.5) in the TCS 1 group, and 15.3 (±5.4) in the TCS 2 group.

Table 13. Baseline characteristics – stroke severity

Characteristic	Control **N = 130**	TCS 1 **N = 132**	TCS 2 **N = 138**
Stroke severity based on Day 5 – 7 BI	14.7 ±5.7	15.5 ±5.5	15.3 ±5.4
Stroke severity – dichotomised BI			
Mild (15-20) - %	80 (61.5)	85 (64.4)	88 (63.8)
Moderate (10-14) - %	25 (19.2)	28 (21.2)	29 (21.0)
Severe (< 10) - %	25 (19.2)	19 (14.4)	21 (15.2)

Stroke type

Stroke type was categorised according to the Oxfordshire Community Stroke Project (OCSP) classification (see Table 14). 41 (10.3%) of index strokes were due to primary intracerebral haemorrhage. The most common type of ischaemic stroke was PACI (n = 135, 33.8%), followed by POCI (n = 127, 31.8%).

Table 14. Baseline characteristics – stroke type

Stroke type (OCSP)	Control N = 130	TCS 1 N = 132	TCS 2 N = 138
PACI – n (%)	46 (35.4)	41 (31.1)	48 (34.8)
POCI – n (%)	38 (29.2)	48 (36.4)	41 (29.7)
LACI – n (%)	29 (22.3)	27 (20.5)	20 (14.5)
PICH – n (%)	12 (9.2)	12 (9.1)	17 (12.3)
TACI – n (%)	4 (3.1)	2 (1.5)	11 (8.0)
Unknown – n (%)	1 (0.8)	2 (1.5)	1 (0.7)

Note - PACI: posterior anterior circulation infarct, POCI: posterior circulation infarct, LACI: lacunar infarct, PICH: primary intracerebral haemorrhage, TACI: total anterior circulation infarct

Stroke risk factors

Within the entire cohort, 62.5% had a history of hypertension, 18.5% had a history of known AF, 17.8% had a history of diabetes mellitus, 17.8% had a previous stroke, and 10.3% had a history of TIA. 5.3% of patients were current smokers at the time of stroke.

Table 15. Baseline characteristics - stroke risk factors

Characteristic	Control	TCS 1	TCS 2
Systolic BP (mmHg) – mean (sd)	140.6 ±19.9	138.9 ±19.6	136.6 ±18.8
Diabetes mellitus – no. (%)	26 (20)	26 (19.7)	24 (17.4)
Body-mass index (kg/m^2) – mean (sd)	28.5±5.5	27.1±4.5	27.2±5.0
Previous stroke – no. (%)	28 (21.5)	22 (16.7)	21 (15.2)
Current smoker – no. (%)	7 (5.4)	6 (4.6)	8 (5.8)

Acute stroke treatment

Groups were similar at baseline for early commencement of aspirin after ischaemic stroke, secondary prevention with a statin, and use of fluoxetine. 49 patients received IV thrombolysis (13.6% of all patients with ischaemic stroke). 6 patients received mechanical thrombectomy (1.7% of all patients with ischaemic stroke).

Table 16. Baseline characteristics - stroke treatment

Treatment	Control	TCS 1	TCS 2
Aspirin within the first 48 hours of stroke (%)	94/118 (79.7)	99/120 (82.5)	90/122 (73.8)
On statin at randomisation (%)	109/130 (83.9)	101/132 (76.5)	113/138 (81.9)
On fluoxetine at randomisation (%)	4/138 (3.1)	7/132 (5.3)	8/138 (5.8)
IV thrombolysis (%)	21/118 (17.8)	10/120 (8.3)	18/122 (14.8)
Thrombectomy (%)	1/118 (0.9)	0/120 (0)	5/122 (4.1)

4.3.3   Other factors

Level of function and rehabilitation input

Mean time from stroke to randomisation was 45.5 days (SD 25.8, range 4 to 125). This was similar across all groups.

Median LOS in acute care (emergency department, medical ward, or acute stroke unit) was 4 days (IQR 3 to 7 days) in all groups. 46/130 (35%) of control, 47/132 (35%) of TCS 1, and 56/138 (40%) of TCS 2 participants received inpatient rehabilitation. Median LOS in inpatient rehabilitation was 19 days (IQR 11-29) in control, 16 days (IQR 9 to 25) in TCS 1, and 15 days (IQR 11.5 to 22.5) in TCS 2. 62% of the study population had outpatient rehabilitation team involvement at the time of trial entry.

Functional dependence at the activity limitation level had improved by the time of the first home visit. 96.2% of control, 93.9% of TCS 1, and 97.8% of TCS 2 participants had a BI of 18-20 at the time of commencement in the study. The mean (SD) Frenchay Activities Index (FAI) at baseline was 23 (10.1) out of a maximum score of 45. This showed significant limitation in extended activities of daily living and potential for improvement over time.

'Living alone' was considered an important variable which was pre-specified and included in the sensitivity analysis of the primary outcome. There was no statistically significant difference at baseline.

Table 17. Baseline characteristics - other factors

	Control **N = 130**	**TCS 1** **N = 132**	**TCS 2** **N = 138**
Barthel Index at randomisation	18.8 ±1.7	18.8 ±2.4	19 ±1.7
Frenchay Activities Index	22.7 ±10	23.6 ±10.2	22.9 ±10.1
Rehabilitation involvement – no. (%)	79 (60.8)	77 (58.3)	92 (66.7)
Lives alone – no. (%)	50 (38.5)	44 (33.3)	42 (30.4)

4.4 Main results

The main results for TaCAS are summarised in Table 18 and Figure 11.

Table 18. TaCAS main results

	ICF level at which Take Charge beneficial	Instrument	Strength of evidence	Effect estimate (95% CI)
Primary outcome	Quality of life at 12 months	PCS of SF-36	Strong	2.9 (0.95 to 4.9)
Secondary outcomes	Quality of life at 6 months	PCS of SF-12	Moderate	2.4 (0.4 to 4.4)
	Participation restriction at 12 months	Frenchay Activities Index	Moderate	2.7 (0.8 to 4.6)
	Activity limitation at 6 months	Barthel Index	Weak	0.5 (0.02 to 0.9)
	Activity limitation at 12 months	Barthel Index	Weak	0.5 (0.04 to 1.0)

Evidence of intervention effect across the domains of ICF
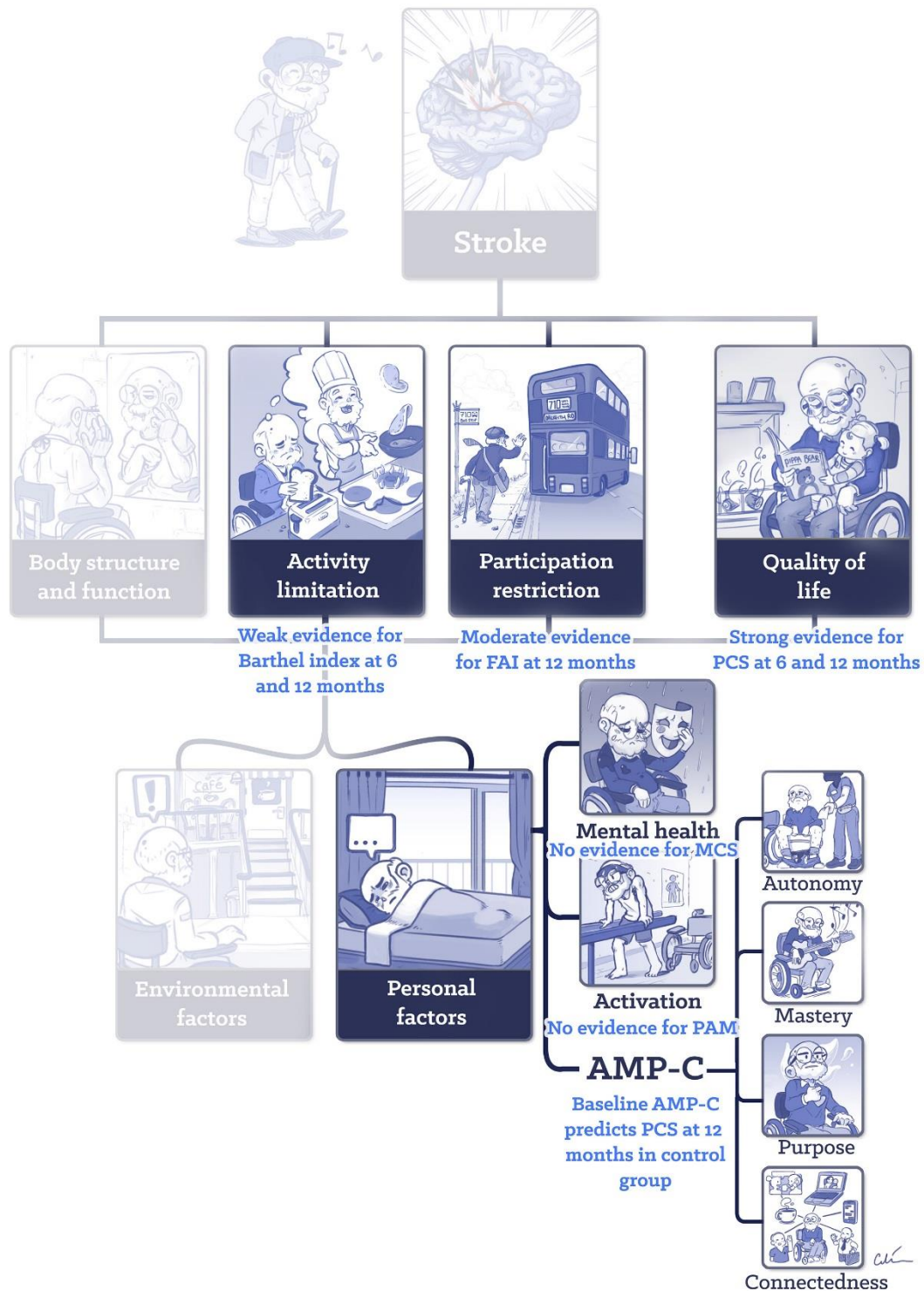
Figure 11. Main effects of Take Charge intervention

Illustration by Dr Ciléin Kearns, Medical Illustrator at the Medical Research Institute of New Zealand

4.4.1   Primary outcome

There was strong evidence of benefit for the Take Charge intervention, on SF-36 PCS at 12 months after index stroke. Compared to control, the point estimate for the combined TCS intervention groups was 2.9 points (95% CI 0.95 to 4.9, p =0.004) higher on the SF-36 PCS. This result is presented in Table 20. Figure 12 displays the results of the primary outcome in each group in boxplot format.

Note about the modification of the Health Transition (HT) question

In the SF-36, the second item is a general health question which asks respondents to rate the amount of change they had experienced in their current health compared with their perceived health status one year ago. Because this was an unweighted question, which did not contribute to any scoring of the eight health domain subscales or the two summary measures, the developers suggested that it could be used as a template to measure a different timeframe of change (Maruish, 2011).

In TaCAS, once the 12-month home visits began, it became immediately apparent that this SF-36 question of 'current health compared to health one year ago' was confusing and ambiguous to participants. It was unclear whether the question was referring to a comparison against the participant's pre-stroke health status, or health during the stroke admission, or health immediately after their stroke, when some participants were experiencing complications from stroke. To mitigate this confusion, after discussion among the research team, the wording of this question was modified to 'current health compared to perceived health six months ago'. This definition gave a more accurate picture of the person's self-perceived trajectory of recovery.

Table 19. Primary analysis ANOVA table –

Main effects of any exposure to Take Charge session

Source	Degrees of Freedom	Sum of squares	Mean Square	F value	P
Model	2	973.4	486.7	5.75	0.0035
Error	378	31968.5	84.6[1]		
Corrected Total	380	32941.8			

[1]Root mean square error: 9.2

Table 20. Effect estimates of TCS on PCS of SF-36 at 12 months

Comparison	Estimate (95% CI)	P
All Take Charge minus Control	2.9 (0.95 to 4.9)	0.004
TCS 2 minus TCS 1	1.9 (-0.34 to 4.2)	0.096

Figure 12. Boxplot of SF-36 PCS vs. randomised treatment at 12 months after stroke

(T1 = TCS 1, T2 = TCS 2)
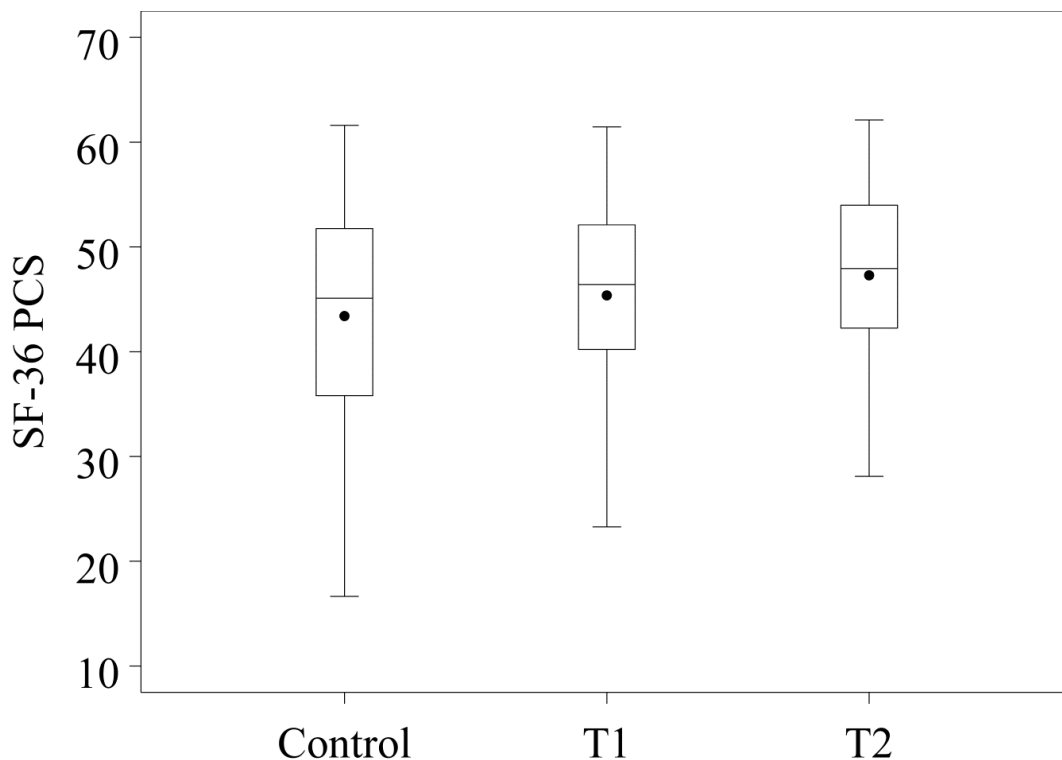
There was evidence of a dose effect with the mean PCS after a single TCS 2.1 points higher than control, and the mean PCS after two TCS 4.0 points higher than control. The effect estimate for the second TCS minus the first TCS was 1.9 (-0.34 to 4.2, p =0.096) however this did not reach statistical significance. This is because this calculation effectively discounted data from the control and TCS 1 groups, leaving the analysis underpowered to detect a difference. A more appropriate calculation of the effect of the TCS as a dose variable is to use ANCOVA. The results of this analysis are presented on page 206.

Table 21. PCS of the SF-36 at 12 months in all groups

(Displayed as mean (SD) and proportion of each group higher than the overall median PCS)

	Control	TCS 1	TCS 2
PCS of the SF-36 at 12 months – mean (sd)	43.4 (10.7)	45.5 (8.4)	47.3 (8.4)
PCS of the SF-36 at 12 months above median of 46.47 – no. (%)	57/125 (45.6)	60/123 (48.8)	74/133 (55.6)

4.4.1.1 Adjusted PCS of SF-36 at 12 months

After adjusting for important baseline covariates (stroke severity, SF-12 PCS, age, gender, and living alone status), the overall difference of 1.8 points (0.15 to 3.5, p =0.032) remained statistically significant. Table 22 shows how the covariates included in this model accounted for approximately one-third of the variation in the primary outcome. With this adjustment, the result has also increased in precision, with narrowing of the confidence intervals, compared to the un-adjusted result.

Table 22. Covariate-adjusted ANCOVA table of PCS of the SF-36 adjusted for Barthel Index 5-7 days after stroke, SF-12 PCS at baseline, age, sex, and whether living alone

Source	DF	Sum of squares	Mean Square	F value	P
Model	7	10811.2	1544.4	26.0	<0.001
Error	369	21941.2	59.5[1]		
Corrected Total	376	32752.3			

[1]Root mean square error: 7.7

Table 23. Effect estimate of PCS of the SF-36 adjusted for Barthel Index 5-7 days after stroke, SF-12 PCS at baseline, age, sex, and whether living alone

Comparison	Estimate (95% CI)	P
All Take Charge minus Control	1.8 (0.15 to 3.5)	0.032
TCS 2 minus TCS 1	1.7 (-0.26 to 3.6)	0.089

4.4.1.2 Treating TCS intervention as a dose variable

When treating the TCS intervention as a dose variable, the dose-response was assumed to be linear. With each increase in number of Take Charge sessions, the 12-month SF-36 PCS increased by 1.9 (95% CI 0.8 to 3.1). This result was statistically significant.

Table 24. ANCOVA table treating TCS intervention as a dose variable

Source	DF	Sum of squares	Mean Square	F value	P
Model	1	973.3	973.3	11.5	<0.001
Error	379	31968.5	84.3[1]		
Corrected Total	380	32941.8			

[1]Root mean square error: 9.2

Table 25. Effect estimate of PCS of SF-36 when treating TCS intervention as a dose variable

Comparison	Estimate (95% CI)	P
Per unit increase in TCS intervention	1.9 (0.8 to 3.1)	<0.001

4.4.1.3 Quintiles of SF-36 PCS

The combined results of the SF-36 were divided into quintiles, and the number and proportion of participants in each band are shown below. Exposure to a TCS conferred an OR of 1.5 of scoring a 12-month SF-36 PCS in a higher quintile compared with no TCS exposure.

Table 26. Quintiles of the SF-36 PCS results – n (%)

SF-36PCS quintiles	Control N=125 (%)	TCS 1 N=123 (%)	TCS 2 N=133 (%)
1 (<37.42)	36 (28.8)	20 (16.8)	20 (15.0)
2 (<44.19)	23 (18.4)	31 (25.2)	22 (16.5)
3 (<48.58)	18 (14.4)	27 (22.0)	31 (23.1)
4 (<53.84)	27 (21.6)	24 (19.5)	25 (18.8)
5 (≥53.84)	21 (16.8)	21 (17.1)	35 (26.3)

Table 27. Effect estimates of likelihood to have a PCS of SF-36 at a higher quintile

(OR > 1 implies more likely to have SF-36 PCS at higher quintile)

P-value for any association 0.028		
Comparison	**Estimate (95% CI)**	**P**
All Take Charge minus Control	1.50 (1.03 to 2.20)	0.035
TCS 2 minus TCS 1	1.43 (0.93 to 2.21)	0.10

4.4.2   Secondary outcomes

There was moderate evidence that the SF-12 PCS at six months was higher compared to control, with the point estimate for the combined Take Charge intervention 2.4 units (95% CI 0.4 to 4.4) higher compared to control.

Table 28. Main effect of treatment on SF-12 PCS at six months – ANOVA table

Source	DF	Sum of squares	Mean Square	F value	P
Model	2	621.0	310.5	3.95	0.02
Error	348	27378.1	78.7[1]		
Corrected Total	350	27999.1			

[1]Root mean square error: 8.9

Table 29. Effect estimate of TCS on SF-12 PCS at six months

Comparison	Estimate (95% CI)	P
All Take Charge minus Control	2.4 (0.4 to 4.4)	0.018

There was moderate evidence that the Frenchay Activities Index (FAI) was better after 12 months by 2.7 units (95% CI 0.8 to 4.6), but not after six months. Table 33 shows that those who were exposed to the TCS had a mean 12-month FAI score that was 2.7 units higher than those who did not receive the TCS. This effect was not statistically significant at six months.

Table 30. Effect of TCS on FAI at six months - ANOVA table

Source	DF	Sum of squares	Mean Square	F value	P
Model	2	186.9	93.5	0.89	0.41
Error	347	36394.0	104.9[1]		
Corrected	349	36580.9			

[1]Root mean square error: 10.2

Table 31. Effect estimate of TCS on FAI at six months

Comparison	Estimate (95% CI)	P
All Take Charge minus Control	1.6 (-0.7 to 3.9)	0.18

Table 32. Effect of TCS on FAI at 12 months - ANOVA table

Source	DF	Sum of squares	Mean Square	F value	P
Model	2	764.4	382.2	4.71	0.01
Error	378	30682.5	81.2[1]		
Corrected Total	380	31446.9			

[1]Root mean square error: 9.0

Table 33. Effect estimate of TCS on FAI at 12 months

Comparison	Estimate (95% CI)	P
All Take Charge minus Control	2.7 (0.8 to 4.6)	0.006

There was moderate evidence the EQ-VAS was better by 5.7 points (95% CI 1.3 to 10.1) after six months between those who had received 2 TCS and those who had only received 1 TCS. This effect was no longer evident after 12 months. There was no difference in EQ-VAS between all TCS minus control at six or 12 months.

Table 34. Effect of TCS on EQ VAS at six months - ANOVA table

Source	DF	Sum of squares	Mean Square	F value	P
Model	2	2094.0	1047.0	3.57	0.029
Error	346	101350.7	292.9		
Corrected Total	348	103444.7			

[1]Root mean square error: 16.8

Table 35. Effect estimate of TCS on FAI at six months

Comparison	Estimate (95% CI)	P
All Take Charge minus Control	1.3 (-2.5 to 5.2)	0.50
TCS 2 minus TCS 1	5.7 (1.3 to 10.1)	0.011

Table 36. Effect of TCS on EQ VAS at 12 months – ANOVA table

Source	DF	Sum of squares	Mean Square	F value	P
Model	2	880.9	440.5	1.57	0.21
Error	364	102171.2	280.7[1]		
Corrected Total	366	103052.1			

[1]Root mean square error: 16.8

Table 37. Effect estimate of TCS on EQ VAS at 12 months

Comparison	Estimate (95% CI)	P
All Take Charge minus Control	2.9 (-0.8 to 6.6)	0.12
TCS 2 minus TCS 1	1.8 (-2.4 to 5.9)	0.41

There was weak evidence that the Barthel Index (BI) was higher in the Take Charge group by 0.5 units after six months and 12 months. There was no evidence of a difference in Carer Strain Index, AMP sum or AMP-C sum between groups.

There was no evidence of a difference by randomisation in any of the ordinal scaled variables: mRS (treated on the ordinal scale), PHQ-2, PAM level, or any of the EuroQol dimensions; where measured at either or both time points.

There was no evidence of a difference in relation to randomisation, for the dichotomous variables: rehabilitation contact, death, readmission, recurrent stroke, or Medication Adherence Questionnaire (MAQ) score at six months or 12 months; where measured at either or both time points. There was a trend towards improvement for the mRS dichotomised at 0-2 compared to 3-5, (TCS 1 + TCS 2 88.0% vs control 80.5%, p = 0.09). Using this difference, the number needed to treat (NNT) with Take Charge for one person to be independent at 12 months was 13.

Table 38. Effect of TCS on BI at six months - ANOVA table

Source	DF	Sum of squares	Mean Square	F value	P
Model	2	22.47	11.2	2.81	0.062
Error	350	1399.0	4.0		
Corrected Total	352	1421.5			

[1]Root mean square error: 2.0

Table 39. Effect estimate of TCS on BI at six months

Comparison	Estimate (95% CI)	P
All Take Charge minus Control	0.5 (0.02 to 0.9)	0.041

Table 40. Effect of TCS on BI at 12 months - ANOVA table

Source	DF	Sum of squares	Mean Square	F value	P
Model	2	25.6	12.8	2.46	0.087
Error	381	1984.2	5.2[1]		
Corrected Total	383	2009.8			

[1]Root mean square error: 2.3

Table 41. Effect estimate of TCS on BI at 12 months

Comparison	Estimate (95% CI)	P
All Take Charge minus Control	0.5 (0.04 to 1.0)	0.033

4.4.3 Sub-group analyses of SF-36 PCS

In the sub-group analyses for the main outcome variable, there was moderate evidence of a greater difference for the two Take Charge interventions combined compared to control for gender, living alone status, and having a support person / main carer (see Figure 13). Table 42, Table 43, and Table 44 show the estimates of effects on the SF-36 PCS of these interaction analyses in general linear models. All tables show the effect calculated from All Take Charge minus control.

Table 42. SF-36 PCS estimates of effects from the interaction model with gender

P-value interaction term 0.01		
Effect estimate	**Estimate (95% CI)**	**P**
Male	0.36 (-2.19 to 2.92)	0.78
Female	6.39 (3.38 to 9.39)	<0.001

Table 43. SF-36 PCS estimates of effects from interaction model with living status

P-value interaction term 0.036		
Effect estimate	**Estimate (95% CI)**	**P**
Lives alone	3.66 (0.40 to 6.92)	0.028
Lives with others	2.39 (-0.08 to 4.85)	0.057

Table 44. SF-36 PCS estimates of effects from the interaction model with having a support person

P-value interaction term 0.02		
Effect estimate	**Estimate (95% CI)**	**P**
Has support person	4.50 (2.20 to 6.80)	<0.001
Does not have a support person	2.39 (-0.08 to 4.85)	0.057

Figure 13. Interaction plot: effect size of PCS of SF-36 in "combined TCS exposure minus control" by subgroups

Overall	2.9 (1.0 to 4.9)
<75 years	1.7 (-0.9 to 4.33)
75+ years	4.0 (1.1 to 6.9)
Fluoxetine	7.2 (1.4 to 13.0)
No fluoxetine	2.4 (0.3 to 4.5)
Communication disorder	7.2 (-10.0 to 16.8)
No Communication disorder	2.8 (0.8 to 4.8)
Cognitive disorder	3.8 (-7.8 to 15.5)
No Cognitive disorder	2.9 (0.9 to 5.0)
Male	0.4 (-2.2 to 2.9)
Female	6.4 (3.4 to 9.4)
Living alone	3.7 (0.4 to 6.9)
Not living alone	2.4 (-0.8 to 4.9)
Support person	4.5 (2.2 to 6.8)
No support person	-1.4 (-5.3 to 2.4)
Ischaemic stroke	2.8 (0.7 to 4.9)
Haemorrhagic stroke	3.8 (-2.5 to 10.1
Thrombolysis	1.6 (-3.9 to 7.0)
No thrombolysis	3.2 (0.9 to 5.4
Tertiary centre	2.7 (0.4 to 5.0)
Non-tertiary centre	3.4 (-0.5 to 7.2)
Barthel mild	3.2 (0.7 to 5.6)
Barthel moderate	2.4 (-2.1 to 6.9)
Barthel severe	2.1 (-2.7 to 6.9)

There was no difference between pre-specified subgroups of: age above or below 75 years, use of fluoxetine at baseline, presence of a significant communication problem, presence of a significant cognitive problem, ischaemic compared to haemorrhagic stroke, treatment with thrombolysis, treatment with thrombectomy, treatment in a tertiary centre, recruitment site, and baseline stroke severity (Day 5-7 Barthel Index) categorised as Mild, Moderate, or Severe disability.

4.4.4   Regression analysis

A regression analysis was performed to determine the relationship between SF-36 PCS and baseline AMP-C score and treatment allocation.

The slope for the change in SF-36 PCS in relation to increasing baseline AMP-C score (assuming a constant slope across all three treatments) was 0.72 (95% CI 0.28 to 1.16, p =0.001). The P-value interaction term of 0.021 was significant for some difference between groups.

Slopes are shown in Figure 14. There was no significant relationship between AMP-C sum and SF-36 at 12 months for the combined and individual treatment groups, TCS 1 and TCS 2. However, the control slope was 1.73 (95% CI 0.90 to 2.56, $p < 0.001$). For those who did not receive the Take Charge session, every one unit increase in the baseline AMP-C sum score predicted a 1.73 unit increase in the SF-36 PCS at 12 months.

Table 45. Estimate of the effect of baseline AMP-C score on PCS at 12 months

Effect estimate	Estimate (95% CI)	P
All Take Charge slope	0.34 (-0.17 to 0.85)	0.19
Control slope	1.73 (0.90 to 2.56)	<0.001

Figure 14. Scatter plot with linear regression lines for relationship between SF-36 PCS and AMP-C sum at baseline by each randomised treatment
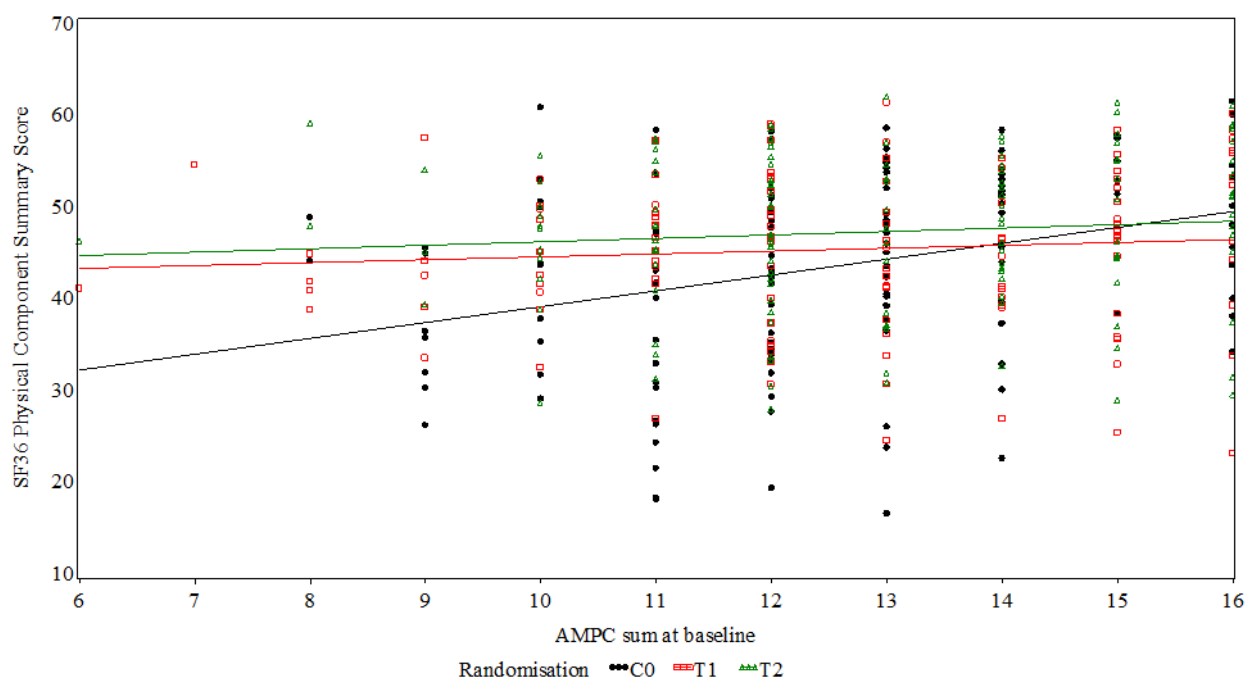
The two relatively horizontal lines represent the two TCS treatment groups, while the lowest horizontal line with a distinctive slope is the linear regression line for the control group. There was no change in the relationship of the SF-36 PCS for the TCS but moderate evidence that as the AMP-C at baseline increased, the control group had a higher SF-36 PCS.

A second regression analysis was performed between the SF-36 PCS, randomisation, and baseline PAM score. The slope (95% CI) for change in SF-36 in relation to increasing baseline PAM score assuming a constant slope across all three instruments is 0.10 (0.03 to 0.17, p = 0.005). For a model with an interaction between randomisation and PAM

score, the P value for the interaction was 0.17, consistent with no difference between randomised groups.

4.4.5   Meta-analysis with MaPSS

An individual patient meta-analysis was performed combining data from TaCAS and MaPSS. The treatment groups were 'Combined TCS' (i.e. TCS 1 + TCS 2) vs control in TaCAS, and 'any treatment containing TCS' vs not in MaPSS. The statistical methodology of this meta-analysis is outlined in the Statistical Analysis section 3.9, page 173.

Table 46 displays simple baseline demographic and risk factor data for participants in both studies, separated into control and Take Charge groups. While both studies were conducted in populations of people with stroke in New Zealand, it is clear from Table 46 and Table 47 that the populations in MaPSS and TaCAS were different from one another.

The TaCAS population was older, was made up of more men, and more of them lived alone. A higher proportions of MaPSS participants had concurrent diabetes, were smokers, and had been diagnosed with previous stroke or ischaemic heart disease. Table 47 shows a summary of the mean results for each rehab instrument measured in each study, separated by exposure to TCS. Note that SF-12 at baseline is not included as this was not measured in MaPSS.

Table 46. Baseline characteristics of TaCAS and MaPSS treatment and control groups

	N/N (%)			
	Control		**Take Charge**	
	MaPSS	TaCAS	MaPSS	TaCAS
Demographics				
Age – mean (SD)	61.5 (14.1)	73 (12.2)	61.3 (13.2)	71.5 (12.6)
African	0	1/130 (0.8)	0	3/270 (1.1)
Asian	0	4/130 (3.1)	0	5/270 (1.9)
Latin American	0	1/130 (0.8)	0	0
Māori	52/87 (59.8)	0	45/85 (52.9)	0
NZ European	0	97/130 (74.6)	0	190/270 (70.4)
Other European	0	27/130 (20.8)	0	72/270 (26.7)
Pacific	35/87 (40.2)	0	40/85 (47.1)	0
Male gender	47/87 (54)	75/130 (57.7)	35/85 (41.2)	159/270 (58.9)
Living alone	18/85 (21.2)	50/130 (38.5)	22/80 (27.5)	86/270 (31.9)
Stroke risk factors				
Diabetes	41/83 (49.4)	26/130 (20)	31/84 (36.9)	50/270 (18.5)
Prev IHD	35/82 (42.7)	33/130 (25.4)	30/82 (36.6)	54/270 (20.0)
Prev stroke	25/86 (29.1)	28/130 (21.5)	19/82 (23.2)	43/270 (15.9)
Current smoker	18/84 (21.4)	7/130 (5.4)	13/84 (22.6)	14/270 (5.2)

Denominators in MaPSS columns change due to incomplete data in MaPSS

IHD = ischaemic heart disease

Table 47. Baseline and outcome rehab measurements in both studies

	Mean (SD)			
	Control		**Take Charge**	
Baseline	MaPSS	TaCAS N = 130	MaPSS	TaCAS N = 270
mRS	2.1 (1.4) N=87	2.0 (0.7)	2.1 (1.3) N=84	1.9 (0.8)
Barthel	16.1 (5.1) N=83	18.8 (1.7)	17.3 (4.1) N=77	18.9 (2.1)
FAI	18.3 (12) N=84	22.7 (10)	21.9 (11.2) N=77	23.2 (10.1)
12 months				
SF-36 PCS	37.8 (11.2) N=61	43.4 (10.7) N=125	43.8 (10.4) N=56	46.4 (8.4) N=256
mRS	1.9 (1.3) N=69	1.5 (1) N=128	1.7 (1.2) N=70	1.4 (0.9) N=259
Barthel	17.4 (4.2) N=66	18.7 (2.8) N=127	18.3 (3.8) N=66	19.2 (2) N=257
FAI	23.6 (11.6) N=65	26 (10) N=126	26.4 (11.4) N=67	28.7 (8.5) N=255
CSI	4.4 (3.5) N=47	3.1 (3.2) N=81	2.9 (3) N=48	3.2 (3.1) N=154
	N/N (%)			
	Control		**Take Charge**	
	MaPSS	TaCAS	MaPSS	TaCAS
mRS <3	41/69 (59.4)	103/128 (80.5)	54/70 (77.1)	228/259 (88.0)

N.B. Denominators change due to incomplete data

Figure 15. Box plot of SF-36 PCS by study and treatment
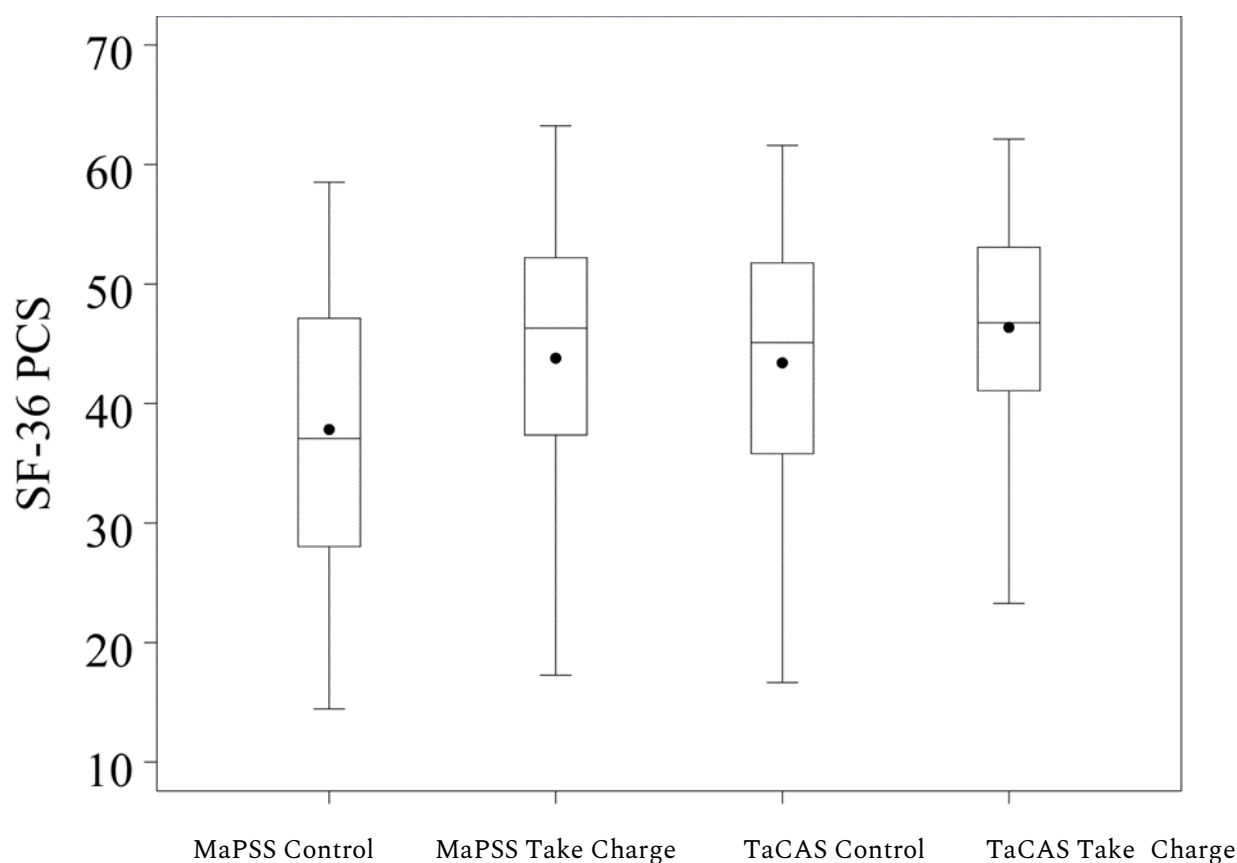
The box plot depicts the range of SF-36 PCS results at 12 months in each study. The symbol represents the mean, and the horizontal line within the box is the median.

To evaluate the continuous outcome variables, a general linear model (ANOVA) was used. We started by testing for an interaction between randomised group and the study source. If this was not statistically significant (i.e. no difference between the two studies), we would estimate the pooled TCS minus control, and MaPSS minus TaCAS differences as main effects. If there was a statistically significant interaction, then the model was used to estimate the effect only of TCS minus control. The P interaction showed no statistically significant differences between the two studies for all the outcome measures except the Caregiver Strain Index.

For SF-36 PCS, BI and FAI: these were all higher (better) in the TCS group than control.

For the same variables, these were all on average lower (worse) in MaPSS than in TaCAS.

This is shown in Table 48.

Table 48. Individual participant meta-analysis

	Estimated difference (95% CI)		P Interaction
Outcome variable	**TCS minus Control**	**MaPSS minus TaCAS**	
SF-36 PCS	3.7 (2.0 to 5.5) $p < 0.001$	-4.0 (-6.0 to -2.0) $p < 0.001$	0.15
Barthel	0.62 (0.11 to 1.1) $p = 0.017$	-1.1 (-1.6 to -0.5) $p < 0.001$	0.54
FAI	2.8 (1.0 to 4.5) $p = 0.002$	-2.4 (-4.3 to -0.4) $p = 0.018$	0.97
	TCS minus Control: MaPSS	**TCS minus Control: TCS**	
CSI	-1.5 (-2.8 to -0.2) $p = 0.023$	0.1 (-0.7 to 1.0) $p = 0.80$	0.04
	Estimated Odds Ratio[1] (95% CI)		
mRS dichotomised <3 versus ≥3	1.97 (1.25 to 3.09) $p = 0.003$	0.40 (0.25 to 0.64) $p < 0.001$	0.59
mRS by ordinal regression	1.32 (0.5 to 1.83) $p = 0.09$	0.55 (0.38 to 0.79) $p = 0.001$	0.27

1. Note a higher odds ratio favours the first-named treatment (i.e. those who received the TCS were more likely to have a lower mRS)

When the mRS was treated as a dichotomous variable, the TCS group had a higher proportion who were independent compared to control, and when treated as an ordinal response variable the point estimate was consistent with a better (lower) score in the TCS group than control. However, this latter association was not statistically significant.

The CSI was lower in the TCS group than the control group in MaPSS but there was no difference between the two groups in TaCAS. This led to a significant interaction term, and only being able to report the TCS minus control effect within each study.

Table 49. Individual participant meta-analysis with estimates for separate studies from an interaction model

SF36-PCS Estimated difference (95% CI)		P Interaction
TCS minus Control : MaPSS	**TCS minus Control : TaCAS**	
5.96 (2.46 to 9.43)	2.97 (0.90 to 5.03)	0.15
TCS minus Control: Pooled		
3.74 (1.96 to 5.51)		

Figure 16. Forest plot of individual study and pooled estimates of the TCS minus control at 12 months after stroke

MaPPS	5.96 (95% CI 2.46 to 9.43)
TACAS	2.97 (95% CI 0.90 to 5.03)
Pooled	3.74 (95% CI 1.96 to 5.51)

0   5   10   15   20

Take Charge minus control SF36-PCS
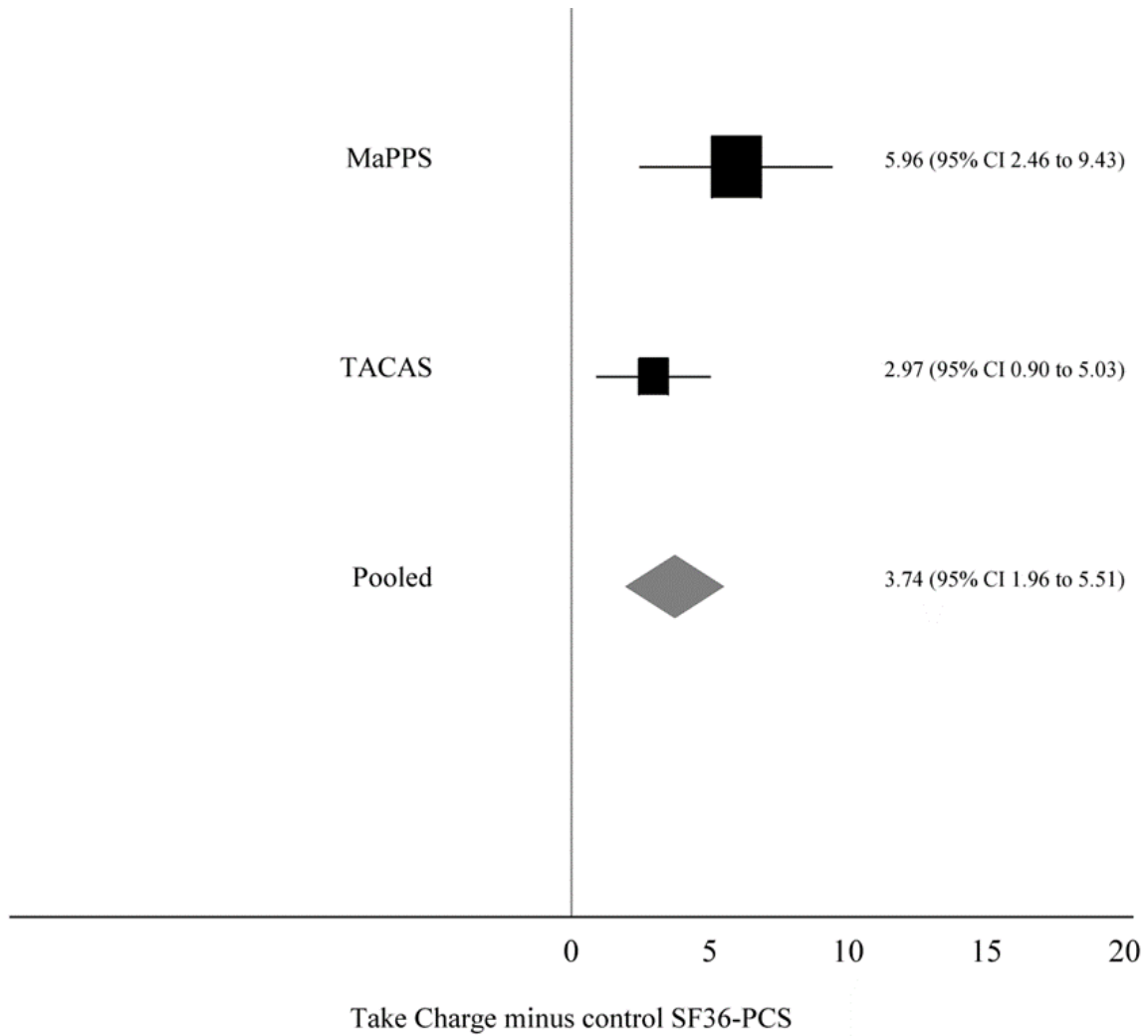
The combined estimated effect of the TCS on the SF-36 PCS was 3.74, when data from TaCAS and MaPSS were pooled. Based on this meta-analysis, a person with stroke who received a Take Charge session would score 3.74 points higher on the SF-36 at 12 months after stroke, compared to a one who did not receive the Take Charge session. This result is a positive effect, which is statistically and clinically significant.

4.4.6 Safety and rehabilitation outcomes

There were no adverse events attributed to the Take Charge intervention. All hospitalisations and deaths were independently reviewed. There were a total of 17 protocol deviation/violations which were minor, and reported to the HDEC.

Readmission within 12 months (combined TCS groups 35.2% compared to control 40.8%, p = 0.09) and recurrent stroke within 12 months (combined TCS groups 5.3% compared to control 7.7%, p = 0.19) were not significantly different.

Ten patients (two control, four TC1, four TC2) died during the follow-up period. Deaths were attributed to cancer (n = 4), sepsis following a fall (n = 1), complications related to severe stroke (n = 1), and 'died at home from natural causes' (n = 4).

Two episodes of inadvertent unmasking of the outcomes assessor occurred at the 12-month visit due to participants leaving their Take Charge booklet out in advance. On both occasions the presence of the booklets was not acknowledged until after data gathering had been completed and the online database locked.

Self-reported rehabilitation contact / involvement at six or 12 months was not significantly different between groups. At 12 months, the odds ratio for having rehabilitation contact was 1.10 (95% CI 0.62 to 1.96, p = 0.75) in both Take Charge groups compared to control.

5 Discussion

We hypothesised that the Take Charge session would be an effective, novel intervention for improving health-related quality of life in community people with stroke, as measured by the PCS of the SF-36. Our second hypothesis was two Take Charge sessions would be more effective than one.

We tested these hypotheses in a multi-centre, single-blinded, randomised controlled trial, in a population of non-Māori, non-Pacific people with stroke in the community. The TaCAS study was designed to answer these two questions and it was adequately powered to do so. Recruitment to the target of 400 participants was achieved close to schedule within 22 months. The trial was completed keeping to the original protocol which was published halfway through the trial (Fu et al., 2017).

All recruiting centres randomised adequate numbers except one (n = 11), suggesting study support for the centres was appropriate. Training of the research clinicians in delivery of the intervention and study procedures was adequate as there was no difference in outcome by centre, and no major loss of data. Randomisation was achieved with no significant differences between groups at baseline.

99.5% of participants were followed up at 12 months. Blinding of the outcomes assessor was rigorous and only two instances of inadvertent un-blinding occurred. Statistical analysis of the trial was pre-specified and published in advance with no important exceptions.

The results from analysis of the primary outcome measure allow us to reject both null hypotheses.

This chapter will now address the following:

1) Whether the results are valid, highlighting the limitations and strengths of the study,

2) Whether the main result is clinically meaningful,

3) Information gleaned from the study about how the Take Charge session works,

4) How the Take Charge session could be used in practice, and finally,

5) Directions for future research that have evolved from performing the TaCAS study

5.1   Validity of the Taking Charge After Stroke Study

5.1.1   The validity of the primary outcome result

The primary outcome of TaCAS indicated that receipt of a Take Charge session (TCS) led to an improvement of 2.9 points in the mean SF-36 PCS, which was statistically significant. There was also moderate evidence for improvement in the SF-12 PCS at six months, and improvement of the FAI at 12 months. There was weak evidence for the BI being higher by 0.5 units after six and 12 months in those exposed to the TCS, compared to those who had not been. Subgroup analysis findings were also interesting and worth discussing further, even though these results cannot be wholly definitive or reliable because of the nature of subgroup analyses.

To begin, I will discuss the clinical relevance of the primary result. It is important to note that rehabilitation contact at six and 12 months was not different between groups, and therefore, the differences in outcomes cannot be explained by one group getting more or less exposure to rehabilitation compared to the others. This section will explore

the validity of the primary result by comparing it first against results from TaCAS, and second, against results from other studies, including MaPSS and the meta-analysis.

5.1.1.1 PCS of the SF-12 at six months

The difference in PCS scores at six months was of similar size and direction to that at 12 months. This result supported the effect of the PCS at 12 months as being a true effect gradually occurring over time. There was moderate evidence that the TCS had noticeable effects on quality of life and participation by six months. The six-month effect estimate of 2.4 was already higher than the estimated MCID of 2.1 derived in Section 5.1.2, making the effect of the TCS clinically, as well as statistically, significant.

Over 98% of the SF-12 data gathered at six months were completed using a paper or electronic questionnaire by the participant. However, because fewer of the 6-month questionnaires were returned compared to the number of completed 12-month home visits, the confidence interval for the estimate of effect is slightly wider than that for the effect estimate of the SF-36 PCS.

That the PCS at six months was already better is a promising result, however. It not only lends extra weight to the result of the PCS at 12 months but also reflects clinically apparent improvements in quality of life and participation for a person with stroke. If the TCS worked by lighting a spark through boosting the recipient's sense of autonomy, then the benefits to wellbeing were apparent by six months. This might also have been a result of having been able to aim for higher level goals and break them down into smaller steps. Potentially achieving some of these smaller goals might have already led to a sense of achievement and purpose, reflected in the score.

5.1.1.2 *Comparing the primary outcome result to MaPSS and the meta-analysis*

The effect estimate for the PCS at 12 months in Take Charge was half that seen in the Māori and Pacific Stroke study (2.9 compared to 6.0), but was in the same direction of positivity. The results, therefore, support each other in providing evidence for the Take charge study's effectiveness at the level of quality of life and participation.

There are likely to be several reasons why the effect of Take Charge was smaller than that seen in MaPSS. One explanation for these results is the inherent downstream effects of colonisation, including institutional and racial bias within the New Zealand health system that continues to lead to ongoing health inequities (Hancock, 2018). Within a health system that is based mostly on European constructs, it is difficult for Māori and Pacific patients to feel a sense of connection with what is happening to them, and what is being done to them when they are afflicted by illness.

For any ethnic group, there is also a greater sense of disempowerment when language is a barrier between the patient and the health professionals who are caring for them.

In the absence of a language barrier, one could infer that the majority of European participants had greater health literacy, and better access to health care in general compared to the participants in MaPSS. Some TaCAS participants held private health insurance, as well as income security insurance, which would have considerably mitigated financial stress due to sick leave from the stroke.

Outside of the health system, the societal effects of colonisation are also apparent when broadly describing the participants in Take Charge. It was clear that while not all the Take Charge participants were particularly well off, they had a socioeconomic advantage compared to the participants in MaPSS. In Take Charge, the majority (80%) of those under the age of 65, and 20% of those older than retirement age, were employed at the

time of the stroke. Those who were working tended to hold professional jobs (e.g. lawyer, accountant, public servant, and police) and jobs in trades. Participants in TaCAS spoke of the holiday homes they would travel to overseas where they could 'get away from it all', 'recuperate', or 'work on the garden'.

This socioeconomic advantage meant that most of the participants in TaCAS had the means to change their circumstances. They were able to afford to join a gym, employ a personal trainer, pay for private physiotherapy, change jobs or reduce their hours, or sign up to courses, such as mindfulness meditation. Instead of feeling as though they had become a burden to others after stroke, it is possible that some participants in TaCAS did not necessarily feel as though having had a stroke had worked against them. Instead, many described the stroke as an event which was a 'wake-up call', and which had given them the drive they needed to change their lifestyle or working conditions.

It is suspected, therefore, that the effect of the Take Charge session in MaPSS would have significantly augmented the autonomy for Māori and Pacific people with stroke toward their inherent psychological needs. The opportunity to be listened to and to be heard by a person of the same ethnicity (as occurred during the Take Charge session) would have been a rare event during the majority of their in-hospital journeys. It is possible that the Take Charge session resulted in Māori and Pasifika being treated differently to how they are usually treated in healthcare, and the nature of the intervention undid some of the effects of systemic bias.

Furthermore, studies in the New Zealand community have revealed that self-reported quality of life in Māori and Pacific people at baseline are lower than that of New Zealand Europeans. In a sampling study of New Zealanders aged 55 to 69, the mean (SD, 95% CI) SF-36 PCS in NZ Europeans was 50.22 (9.60, 95% CI 49.92 – 50.52); in Māori was 47.39 (10.60, 95% CI 46.37 – 48.42); and in Pasifika 42.51 (8.78, 95% CI 41.13 – 43.89) (Stephens,

Alpass, Baars, Towers, & Stevenson, 2010). Although the SF-36 does not have a significant ceiling effect, if the mean of 50 on the PCS is considered to represent the mean in a 'normal healthy population', then the 'norm' for Māori and Pasifika is less than that of their European counterparts. It only stands to reason that those who start at a lower baseline have greater room to improve, once conditions they find themselves in support this occurring.

The differences between the mean PCS in both treatment and control groups in the two studies support this argument. The reason the PCS effect size in MaPSS was so much larger than it was in TaCAS was not that the treatment group PCS in MaPSS was higher than that in TaCAS. In fact, the final PCS in both groups that received one TCS were remarkably similar in the two studies (see Table 50). The difference in effect size was due to participants in MaPSS doing so much more poorly when they received usual care.

Table 50. Differences between SF-36 PCS in control vs treatment groups in MaPSS and TaCAS

	Mean (SD) PCS in control at 12m	Mean (SD) PCS in TCS 1 at 12m
MaPSS	35.9 (10.1)	44.8 (10.4)
TaCAS	43.4 (10.7)	45.4 (8.4)

It is not surprising that within rehabilitation services, Māori and Pacific patients experience diminished autonomy, a reduced sense of mastery, and uncertain purpose within a predominantly Pākehā narrative. While the DVD that was produced in MaPSS had attempted to turn these concepts around, that particular intervention had not been effective. It would be fair to say then, that something powerful happened when Māori and Pacific patients received the Take Charge session, something that emerged from the 'person – whānau – ethnically appropriate research clinician' axis that sparked the person to take charge.

Efforts to achieve health equity in Aotearoa New Zealand are ongoing. It would be interesting to see what effect larger doses of the Take Charge session may have in Māori and Pasifika people with stroke.

Another explanation for the difference in effect size between the two studies is the possibility that the effect of Take Charge in TaCAS was dampened by some of the research clinicians having expertise in traditional rehabilitation (albeit fewer than half of the total RCs). Because the Take Charge sessions were not monitored or standardised at each site, it is possible that any inclusion of traditional rehabilitation methods, such as the prescription of task-based activities or inadvertent clinician involvement in goal setting, could have diluted the effects of the intervention. By contrast, the research assistants in MaPSS had backgrounds in community health or community nursing, so that crossover into traditional rehabilitation practice would have had a lower chance of occurring.

5.1.1.3   Frenchay Activities Index at 6 and 12 months

The higher PCS at six months discussed in the previous section was unlikely to have been caused by increased participation because the FAI at six months showed no

difference between TCS groups and control. At six months, all participants were still participating socially at relatively similar levels.

The effect of the Take Charge session on participation was only apparent at 12 months, when participants who had received the TCS had a 2.7 point higher mean FAI compared to those who had not received it. These results could be interpreted as social participation and function requiring greater time to be improved. In addition, an important phenomenon was observed. Because quality of life *was* improved by six months, even though participation was *not*, one could infer that the improvement in quality of life was due to improvement at some other level of the ICF, or in some other dimension. For example, it could have been due to a change in personal factors, by re-affirming purpose and autonomy, as mentioned in the previous section.

However, on review of the actual numbers, it is apparent that while the mean FAI at six months is very similar between groups, all the values are all slightly higher than the mean FAI at 12 months in all groups. This leads one to question whether the method of obtaining data contributed to the difference. It is unlikely that participation reduced slightly at 12 months across the board as one would expect participation to improve over time.

The majority of six-month data came from paper or electronic questionnaires completed by participants. While the components of the instrument are supposed to be objective (how frequently the person engaged in the activity in recent months), the method of completion introduced a subjective element. Tooth and colleagues had shown that patients tended to score themselves higher than proxies (Tooth et al., 2003). On the other hand, the 12-month data were obtained through direct, face-to-face questioning. Often this was done in the presence of other family members, and with additional explanation and clarification to aid the participant's understanding of the question. It is, therefore,

possible that the 12-month responses were more objective, and more honestly reflected the person's true level of participation, given these different circumstances in which the instrument was used. This may also be why the difference between groups was only observed at 12 months.

5.1.1.4 Barthel Index at 6 and 12 months

The mean BI was higher by 0.5 in the combined groups that received the TCS, compared with control, at 6 and 12 months. Although the Take Charge session was not targeted at improving function at the level of activity limitation, there were small differences between groups. Due to the high BI in all groups at baseline, the BI would have had low sensitivity to change and any change would have been limited by its ceiling effect. The 0.5 point difference was not clinically significant.

5.1.1.5 No effect on mental health measures

The Take Charge session had no effect on the MCS at six or 12 months, nor the PHQ-2 at six or 12 months. The former result was unsurprising, because the TCS had shown no effect on the MCS in MaPSS. Because the TCS was largely a psychological intervention, we were uncertain as to whether the PHQ-2 would be affected.

There are several possible explanations for these results. The PHQ-2 has a wide range of sensitivity depending upon the score (between 61-86%) (Arroll et al., 2010). It is most commonly used as a screening tool in primary care for major depressive disorder, and the Take Charge session was not a psychiatric or behavioural intervention aimed at treating depression. So, the PHQ-2 was probably not sensitive to whatever small changes the Take Charge session might have made to a person's mood.

The PHQ-2 was included to ensure that any differences between groups in the primary outcome, (or, indeed, if there had been a difference in the MCS between groups), would not have been accounted for by differences in rates of depression that occurred by chance.

The effect of the Take Charge session was probably manifested through an increase in a person's sense of purpose, autonomy, mastery, and connectedness. The MCS was not likely to have been sensitive to any of these factors because they were not explicitly measured by any items that contributed to the mental health subscales in the SF-36. Furthermore, we know from previous studies that the Social Functioning subscale of the SF-36 has poor internal consistency, and as we have seen, an increase in social functioning (as measured by the FAI) was not observed until at least 12 months after stroke.

No known self-management interventions have affected SF-36 MCS levels in people after stroke. One would argue that this is more likely to be a reflection on the sensitivity of the scale and the summary score, and the relevance of the measured items to people with stroke, rather than the tested interventions.

5.1.1.6 Pre-specified subgroup analyses

These results need to be interpreted with caution, even though the analyses were pre-specified in the statistical plan of the trial registry and in the published protocol. That there was a relatively large, positive effect of the Take Charge session in females was not a result that had been predicted nor expected. Therefore, the finding cannot be presumed to support an underlying hypothesis. This result does, however, generate a hypothesis that perhaps the Take Charge session may be more effective in females.

Similarly, the result for living status was surprising. It had been unclear whether the Take Charge session being positive in MaPSS had been related in part to a greater proportion of Māori and Pacific people with stroke living with others. Previous literature had shown that living alone after stroke was associated with increased long-term mortality (Redfors et al., 2016). We had hypothesised that living alone would predict a worse outcome, but the results from this subgroup analysis did not support this.

The third subgroup analysis with a positive finding did support a hypothesis, that is, that having a support person would confer a better outcome. However, it would be most appropriate to interpret the subgroup analyses with the assumption that the main result of TaCAS applies to the entire study population. This is because the Take Charge session also had a moderate effect size in those who did not have a support person. This result trended toward, but did not reach, statistical significance.

5.1.2   Deriving the MCID for SF-36 PCS in stroke

The main result of TaCAS showed a clear response of the SF-36 PCS to exposure to a Take Charge session. However, this numerical improvement is difficult to visualise because the SF-36 is not a simple, ordinal measure, but a rather complex one. More importantly, it does not reveal what the difference of 2.9 units on the 0-100 scale of the PCS translates to in real life. What does a change of 2.9 units mean to a person with stroke? Is it clinically meaningful?

The most reliable way of establishing the clinical significance of this change is to estimate the minimal clinically important difference (MCID) of the SF-36 PCS in people with stroke using a statistical model. Conceptually, the MCID is a simple idea, that is, the smallest change in a clinical outcome that a patient would identify as important.

Applied in this context, the MCID would be the smallest change in the PCS that would be discernible and important to a person with stroke.

There are three methods to determine the MCID:
- Distribution-based methods, a statistical derivation based on data spread and effect size
- Anchor-based methods, which compare changes in a scale with an 'anchor' question (or questions) as a reference to determine if the patient feels better or worse compared with a baseline, according to the patient's own experience
- The Delphi method, which relies on a panel of experts who reach a consensus about the MCID.

Our preferred approach was the anchor-based method for two reasons: first, it took into account the perspective of the patient, which is the primary intent of the MCID, and second, unlike the Delphi approach, it is quick and based on objective evidence. We were able to use existing data that had been gathered from our participants for statistical modelling. It was fortunate that inbuilt into the SF-36 was a question about perceived health change, which did not contribute to the final scores of either the PCS or the MCS. The question is shown in Figure 17.

Figure 17. Modified perceived health change question in SF-36v2

Compared to 6 months ago, how would you rate your health in general now?

Much better now than 6 months ago	Somewhat better now than 6 months ago	About the same as 6 months ago	Somewhat worse now than 6 months ago	Much worse now than 6 months ago
▼	▼	▼	▼	▼
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Note that in the original form, the question read "Compared to one year ago …" and the responses correspondingly read "Much better than one year ago" etc. However, it was apparent in the first 12-month home visit that the wording of this question was confusing. It was unclear whether the comparison of their current health state was being made against the person with stroke's pre-stroke state, or their state immediately after their stroke, or in the early days to weeks of recovery. To eliminate this ambiguity, and because this response had no weight in the final calculations of PCS or MCS, we took the liberty of modifying the timeframe to six months.

Choosing this time point allowed us to compare the six-month SF-12 PCS results and the 12-month SF-36 PCS results, treated as being on the same scale, using the above health change question as an external 'anchor'. Linear regression was used to estimate the relationship between SF-36 PCS or the derived variable of "SF-36 PCS minus SF-12 PCS at six months" and the ordinal scale variable of health change, treating the difference between each level as a one unit change. SAS version 9.4 was used.

Table 51 shows that the relationship between health change and the SF-36 PCS was a little complex, with a drop of about 2 points from Much Better to Somewhat Better and Same, and quite a significant drop down to Somewhat Worse of about six points. There was an average drop per level of about 3 points. The relationship is more clearly illustrated in the box plot Figure 18.

Table 51. SF-36 PCS by health change category

Health change at 12 months	SF-36 PCS Mean (SD)
1=Much Better N=110	48.3 (8.2)
2=Somewhat Better N=106	46.2 (8.3)
3=Same N=107	46.4 (8.8)
4=Somewhat Worse N=55	37.4 (8.4)
5=Much Worse N=3	22.2 (4.3)

Table 52. Change in mean PCS over six months by health change

Health change at 12 months	Mean (SD) SF36-PCS minus SF12-PCS at 6 months
1=Much Better N=101	4.2 (7.1)
2=Somewhat Better N=94	2.6 (6.3)
3=Same N=99	1.2 (6.9)
4=Somewhat Worse N=50	-2.4 (6.5)
5=Much Worse N=3	-8.9 (11.1)

(N.B. Fewer six-month follow-up results were available than at 12 months)

Table 53. Linear regression treating each level of health status as one unit difference

Variable	Increase in SF36-PCS per change in level of variable	P
Health change	3.0 (2.2 to 3.9)	<0.001

	Increase in SF36-PCS minus SF12-PCS per change in level of variable	
Health change	2.1 (1.4 to 2.8)	<0.001

Figure 18. Boxplot of 12-month PCS against health change at 12 months
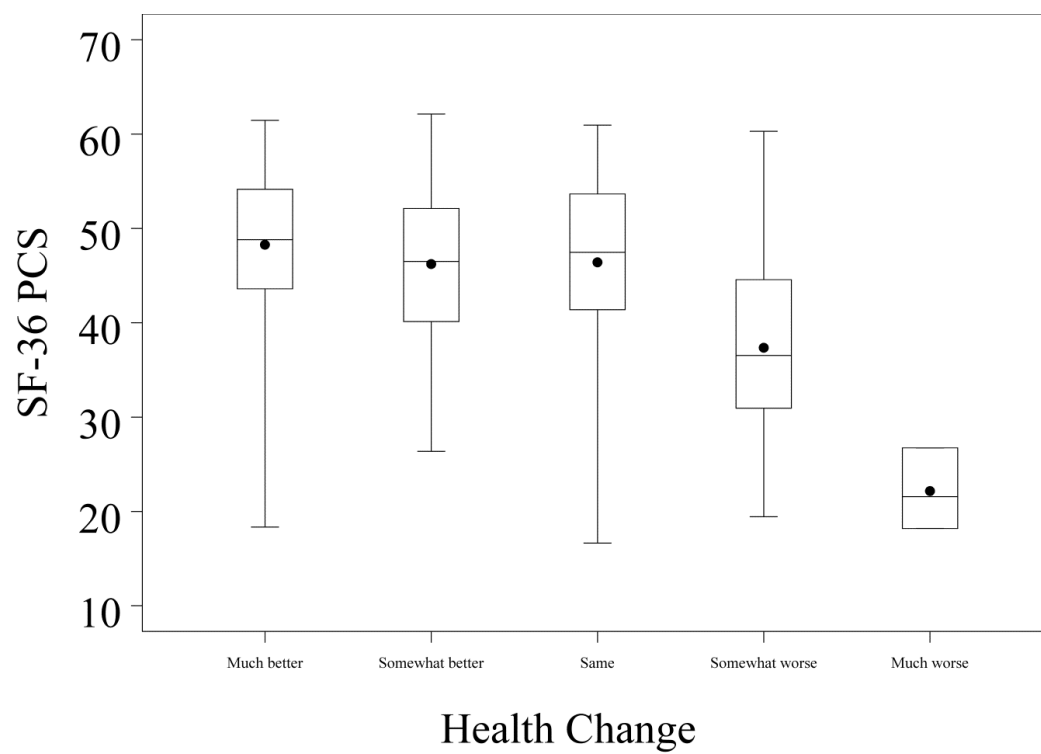
Figure 19. Boxplot of difference between six-month and 12-month PCS against health change at 12 months
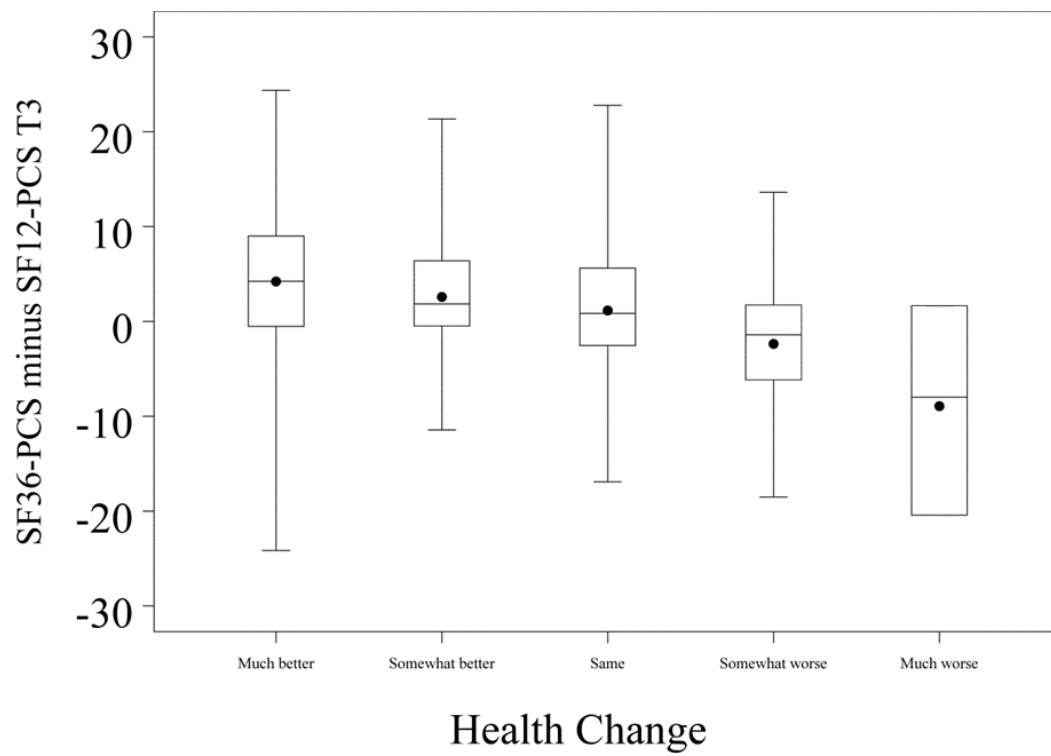
The comparability of the PCS-12 and PCS-36 has been cross-validated using data from general population surveys in multiple countries (Gandek et al., 1998). Pearson correlation coefficient between SF-36 and SF-12 summary measures were very high, ranging from 0.94 to 0.96 for PCS. Mean SF-36 summary measures and their SF-12 counterparts were within 0.0 to 1.5 points (median 0.5 points) in each country and were comparable across age groups. Norm-based scoring and a fixed population-based mean of 50 (SD 10) allowed us to treat the SF-36 PCS and SF-12 PCS as being on the same scale.

Table 54. Description of physical differences between SF-36 PCS scores

SF-36 PCS mean	Description
40	Some to a lot of difficulty with moderate activities like moving a table, pushing a vacuum cleaner, lifting groceries. Some difficulty climbing several flights of stairs. Pain interferes moderately with daily life.
42.1	A little bit of difficulty with moderate activities, and climbing several flights of stairs. Able to climb one flight of stairs with no limitations, but limited by physical ability at least some of the time.
44.2	No problems with moderate activities limited a little to a lot in doing vigorous activities, such as running, lifting heavy objects. Mild pain interfering with daily life a little of the time.

Moving between each level of self-assessed health change was associated with a 2.1 unit change in the PCS (see Table 53), and this is the best estimate of the MCID of the PCS in our study population. As an example, this is equivalent to a person's perceived health

change as moving from "somewhat better now than six months ago" to "much better now than six months ago". Therefore, the 2.9 unit change in the mean PCS after exposure to the Take Charge session is clinically significant.

To illustrate the 2.1 difference in clinical terms, the descriptions in Table 54 came from sampling responses from TaCAS participant data, comparing the mean PCS of SF-36 of 40, 42.1, and 44.2.

In keeping with MaPSS, the PCS of the SF-36 was chosen as the primary outcome as it is a commonly used health-related quality of life measure in multiple conditions, and has demonstrated robust psychometric properties when tested in people with chronic stroke. Because of norm-based scoring, it is relatively simple to relate results to different populations, including that of well, healthy individuals. Being able to define an MCID of the PCS from our data has been a strength of this trial.

By doing this we were able to show that Take Charge was effective at improving health-related quality of life and participation restriction up to 12 months after stroke, and the result was clinically meaningful. The next section will explore strengths of the study.

5.1.3 Strengths

The strengths of this study were adequate, robust randomisation and data management procedures, masked outcome assessment, adequate length of follow-up with outcomes measured at 12 months after stroke to ensure a sustained response, and excellent follow-up rate.

5.1.3.1 Adequate size

TaCAS was a large, rigorously conducted RCT. The TaCAS trial successfully reproduced MaPSS, in a much larger population with high rates of follow-up. It was adequately powered to detect a clinically meaningful difference in the primary outcome. Furthermore, TaCAS was able to show that the Take Charge intervention was effective in people with stroke of different ethnicities from those in MaPSS and that two TCS were more effective than one. With both trials complete, data are now available for the TCS tested in 572 people.

Apart from one centre that randomised only 11 participants, all other sites randomised a minimum of 27 participants. This high rate of enrolment at each centre ensured adequate dilution of any 'learning curve' for the RCs who were delivering a novel intervention.

5.1.3.2 Randomisation and data management

The process of randomisation was robust and provided little room for error or tampering with opaque envelopes. This was confirmed by well-matched baseline characteristics across all groups.

An electronic database safeguarded data integrity of TaCAS. The database allowed all of the following: participants to complete the 6-month questionnaire online, direct source data entry at the 12-month visit, centralised monitoring, double data entry, and reconciliation. The research clinicians (RCs) gathered source data on paper forms at the initial home visits. They sent copies of de-identified source data to the MRINZ for data entry and monitoring. Data queries were dealt with promptly resulting in comprehensive data with minimal data loss. Six-month questionnaires that were received by post were followed-up with participants by telephone, and uncertain responses were clarified.

The methods of masking of the outcomes assessor as to treatment allocation were rigorous. Password-protected user rights in the software prevented the assessor from viewing any data other than demographic information and the 12-month questionnaire. The network folder containing the randomisation schedule and screening logs was kept invisible to the assessor on the research institute's main server. RCs and data management staff were physically located in separate offices, and source data were kept in locked filing cabinets to which the assessor had no access. At each site, RCs reminded their participants not to discuss the initial visits with the assessor. This message was reiterated in the 12-month appointment letters which were posted to participants. With these measures in place, only two instances of inadvertent unmasking occurred when participants left the 'Take Charge' booklet in view. At these visits, the booklet was disregarded entirely until data were entered electronically and locked against further editing.

The primary outcome measure and most of the secondary measures were self-report. This limited the potential for assessor bias by the external, blinded assessor. However, it is acknowledged that the nature of the interventions meant participants were not blinded to allocation. This introduced a potential element of assessor bias by the participants in the self-reporting of their outcomes.

5.1.3.3 High follow-up

TaCAS had high rates of follow-up at 12 months; primary outcome data were obtained in 380 participants (95% follow-up). Some secondary data were obtainable for 390 participants (97.5% follow-up). The minimal sample size of 360 required to have 90% power to detect a difference of 5.0 points in the PCS was exceeded. Moreover, the same, masked assessor completed the 12-month follow-ups on all the participants, minimising concerns about the inter-rater reliability of the instruments.

The window for accepting responses for the 6-month questionnaires was ±14 days from the six month anniversary of the date of stroke. An electronic version of the questionnaire was developed through the REDCap database with the aim of increasing uptake (Harris et al., 2009). Vigorous monitoring of due dates and follow-up with telephone calls were used to remind or assist participants with completing the questionnaires. Despite these measures, 6-month questionnaire data were missing for 10.75% of all participants likely due to the nature of self-administered questionnaires. Follow-up at 12 months was substantially better because it was an arranged home visit with a wider, more flexible time frame of – 4 weeks to + 6 weeks after the 1-year anniversary of the date of stroke.

5.1.4   Limitations

The TaCAS study has several weaknesses. Some of these were able to be controlled for, and some were due to chance. However, these weaknesses need to be highlighted because they raise the question of whether or not the results are generalisable. These limitations were baseline imbalance between groups for important variables, uncertainty about how consistent delivery of the Take Charge session was between sites and research clinicians, selection bias, contamination, and limitations with the outcome instruments.

5.1.4.1 *Baseline imbalance for PCS and dependence*
While there were no statistically significant differences in any covariates at baseline, there were small differences between groups that warrant mentioning. The main differences were that in the control group, first, the mean SF-12 PCS was lower (worse), and second, there was a higher proportion of participants who were dependent (modified

Rankin scale > 2) compared to the two treatment arms. At the baseline home visits, the SF-12, modified Rankin scale, and all other assessments were completed before randomisation. Therefore, it is most likely that both these baseline imbalances occurred due to chance.

The mean (SD) SF-12 PCS at baseline was 40 (8.5) in the control group, 41 (7.6) in TCS 1, and 41.9 (8.2) in the TCS 2 arm. The meaning and impact of the SF-12 PCS baseline imbalance on the overall results are uncertain because the scientifically meaningful differences of this scale (and many others that were measured) are unknown. Considered in the light of our MCID calculation for SF-36 PCS (see 5.1.2, page 238), the baseline imbalances in mean SF-12 PCS would not be clinically significant between groups.

We recognised that the SF-12 PCS at baseline was an important variable that could affect the primary outcome result, and therefore its effect on the SF-36 PCS at 12 months was pre-specified in the sensitivity analysis. The sensitivity analysis showed that the effect estimate for the Take Charge session was still positive and statistically significant after controlling for SF-12 PCS, and other variables such as age and gender.

The number (%) of participants who were dependent (mRS > 2) at baseline was 33 (25.4) in the control, 24 (18.2) in TCS 1 and 33 (23.9) in TCS 2. Purely for illustrative purposes, this baseline variable was compared using the Chi-square test, and there were no statistically significant differences between groups (p = 0.33). The overall imbalance was minor.

Considering other baseline instruments which have more sensitive psychometric properties aids the interpretation of this finding. For example, the difference in the proportion of dependent participants between groups was not reflected in a difference in mean baseline Barthel Index (also a measure of dependence, but more specifically at the

level of activity restriction on the ICF), nor in a difference in mean baseline Frenchay Activities Index (extended activities of daily living, i.e. participation).

At trial entry, the mean (SD) Barthel Index was 18.8 (1.7) for control, 18.8 (2.4) for TCS 1, and 19.0 (1.7) in TCS 2. The mean (SD) Frenchay Activities Index was 22.7 (10) in control, 23.6 (10.2) in TCS 1, and 22.9 (10.1) in TCS 2. In individual patients with chronic stroke, the 'smallest real difference' (SRD) in the FAI is a 6.7 change score (Lu et al., 2012). Both these instruments reveal a lot more about a participant's level of function than the simple mRS. Because our intervention was primed to act upon the levels of participation and quality of life, a slight difference in baseline mRS is of lesser importance if the mean BI and FAI are well-matched at baseline.

5.1.4.2   *The consistency of delivery of the Take Charge session*

Another weakness was our inability to ensure that the intervention was delivered uniformly across all sites. TaCAS was a multi-centre trial, and the Take Charge session was delivered by one to two different research clinicians (RCs) per centre (see Table 7, page 181).

To encourage consistency, the RCs were trained by the same Principal Investigator (Dr Harry McNaughton), using the same teaching materials, content, and TCS. After study initiation, external site RCs raised early questions about delivering specific components of the TCS. For example, many participants expressed reluctance at using supplied crayons to draw on the 'My Best Day' page. The study team promptly addressed these queries via teleconference. Within a few months of study initiation, the main RC at the Wellington/Hutt central site (Judith Riley) became expert at delivering the TCS. This RC continued to support colleagues at external sites via telephone and e-mail.

It would have been preferable if our main RC had been able to attend the Take Charge session delivered by the RCs at other sites. Observing, debriefing, and feeding back immediately after each session might have improved consistency. We also considered filming our main RC while she delivered the Take Charge session to several participants and distributing this clip to the other RCs as an anchoring tool. A more resource-heavy alternative would have been to film each RC while they delivered the Take Charge session, and provide feedback to ensure consistency.

The first option became too difficult to coordinate as recruitment intensified quickly at our main site and the main RC was needed to conduct V1 and V2 home visits. There was no time to spare for her to visit external site RCs. The other options would have required further applications to ethics, changes made to the consent documentation, and funding and setup for videotaping at participant's homes. However, we recognise the importance of producing a demonstration video such as 'How to Deliver a TCS' as being a valuable resource for the training of others in the future (Riley et al., 2017).

We were reassured that there were no significant differences across the seven centres in the effect estimate of the PCS which suggested that training had been appropriate and quality of the interventions had been consistent. Furthermore, leaving the development of the RC-patient relationship up to the RC and the participant without providing a 'script' for how this should occur was probably beneficial overall. The RCs reported that getting to learn how to deliver the Take Charge session was a process of becoming familiar with its concepts, and seeing the effects of their interactions with patients from a different perspective (Riley et al., 2017). Those with a rehabilitation background especially realised when they had inadvertently given advice in their early sessions, and worked to change this habit.

5.1.4.3   Selection bias

The terms of ethics approval for TaCAS required that to be eligible, participants had to be able to give fully informed consent. Use of a proxy consent was not allowed. This factor inevitably led to the investigators being unable to approach patients with moderate to severe stroke deficits affecting alertness, cognition, and communication. Therefore, the randomised population in TaCAS was skewed toward people with milder stroke.

This bias has two important consequences. First, the TaCAS population started at a better level of function at baseline compared to the general population of people with stroke. Second, from a measurement perspective, instruments with a significant ceiling effect, such as the BI, were not expected to show major change between treatment groups nor over time. However, we can say that the Take Charge session was able to significantly change the PCS in people with stroke with milder stroke and better baseline function than in MaPSS.   This makes the results even more generalisable to the New Zealand population with stroke over and above MaPSS.   Generalisability increases further if the data from both studies are combined.

Over 90% of TaCAS participants identified with European ethnicity, which was an over-representation of the 71% of New Zealanders who identified as European in the 2013 NZ Census (Statistics New Zealand, 2014). Compared with MaPSS, our study population on average were older, had slightly more men than women, and were recruited after their first-ever stroke. A greater proportion of the TaCAS population lived alone and were independent at baseline. The TaCAS population also started with a higher PCS at randomisation.

The results of TaCAS are, therefore, generalisable to the majority of New Zealand people with stroke. An even greater proportion of New Zealand's ethnicities are accounted for when results are combined with those from MaPSS.

However, because of limited funding, we were unable to afford translators to support the recruitment of patients who were unable to speak in English. We were unable to generalise the results of TaCAS to people of Asian, Middle Eastern, Latin American, or African descent. In 2013, Asians alone made up 11.8% of the New Zealand population. By 2038, the Asian population is predicted to increase to 22% of the New Zealand population, Māori are also predicted to increase from 16 to 18%, and Pasifika from 8 to 10% (Statistics New Zealand, 2017). Therefore, future research about the Take Charge session should make a greater effort to include participants from minority groups.

5.1.4.4 Timing of interventions

It may be argued that we allowed too much flexibility in the timing of V1 for the value of the intervention to be deemed effective at modifying outcomes for all participants. Indeed, we allowed a wide window of timing of the first visit from the date of stroke, to include as many eligible participants as possible. Our ideal timing for the intervention was *"as early as possible in the community phase of stroke"* (see Section 3.5.3: Timing of the first visit, page 132).

Those who were seen in the early weeks after stroke were usually people with mild stroke who were discharged after a very short admission to hospital, or who were not admitted to hospital at all. Some patients were discharged directly from the emergency department, and the neurology team referred a small number of patients to the TaCAS study team after they had been seen in the TIA clinic and diagnosed with stroke. These individuals had been managing to live in their own homes prior to their clinic appointment and so were not admitted to hospital. They received investigations and

management as outpatients. Two patients were seen earlier than one week, as their symptoms had been relatively mild and they felt ready and able to participate. One was randomised at four days, and the other at six days after stroke.

At the maximal end of our first visit window, we accepted patients who were randomised up to 16 – 18 weeks after stroke. If, for some reason, the patient had to postpone their original appointment, for example, because of illness, we allowed the first visit to take place at up to 18 weeks. A total of six patients were seen between 16 to 18 weeks, which was a small proportion overall. There were several reasons why conducting the intervention this late was believed to be beneficial rather than detrimental.

First, the purpose of the Take Charge session was to effect change at the levels of function, participation, and quality of life. The Copenhagen Stroke Study showed that 95% of neurological recovery and best ADL function occurs most within the first 12 weeks after stroke, but recovery of participatory and social function is an ongoing process that can take months to years (Jørgensen et al., 1995). Stroke recovery is not only about recovering motor ability, strength, or coordination.

Since Take Charge was not expected to have any impact at the impairment or body structure and function levels, not intervening within 12 weeks was not an issue. Because most patients would have reached maximal motor recovery by 12 weeks, we also predicted that discharge from inpatient rehabilitation would coincide with this timeframe.

In TaCAS, many people seen at 12 months after stroke were still working towards returning to meaningful hours of employment and increasing activity levels. Hence, the timing of the Take Charge session could be seen as coinciding with the time when the focus moved from the treatment of bodily functions and impairment, to improving levels of activity and participation. The wide window for randomisation allowed us to

maximise inclusion of patients with more severe stroke who might have required a longer admission to inpatient rehabilitation to enable them to be discharged home.

Second, the Take Charge session was designed as an intervention meant to benefit those who lived in the community. Cutting off our treatment window early would have caused a large number of people who needed longer time in inpatient rehabilitation prior to their transition home to be excluded. It would not have made sense to exclude people who needed rehabilitation in order to manage to live at home with stroke because these individuals were those whom the Take Charge session was designed to help the most. The Copenhagen Stroke Study showed that the best ADL function was reached within 17 weeks in patients with initially very severe disability (Jørgensen et al., 1995). Knowing that our trial design was biased toward enrolling patients with milder stroke, we wanted to maximise the inclusion of patients with moderate to severe stroke as much as possible, so that trial results would be generalisable.

Third, the Take Charge session was a person-centred intervention. Only by allowing time for people to live within their own environment could they honestly experience how they felt about themselves, their daily life, and the future they envisaged. Challenges and successes were their own, unique experiences. This is also why the Take Charge session was home-based, and not considered appropriate for testing within the inpatient rehabilitation unit. Allowing an extra four to six weeks gave the patient and their family time to settle into life at home, to recover from the emotional fatigue of being in hospital, and to notice any improvements or difficulties when living within their own environment.

Finally, the duration of the Take Charge session remained the same as it was in the Māori and Pacific Stroke Study. Since it was a successful intervention in MaPSS, and

TaCAS was an attempt to reproduce the same effect, it made sense to keep the timing of the intervention relatively unchanged.

5.1.4.5   Screening

The screening of patients for eligibility varied across sites. The primary sites (Wellington and Hutt) kept a screening log and actively screened patients almost every day. Due to differences in staff structure, some of the other sites had to rely on referrals from inpatient stroke or rehabilitation services. At one site (Auckland), patients were screened by a research team who had to recruit participants for concurrent trials. Hence, although that site was a high-volume centre, only a relatively small number of patients were enrolled in TaCAS. Nevertheless, the baseline characteristics of the trial population were comparable to those of the overall New Zealand population with stroke, except for ethnicity and the bias towards milder stroke, which has already been discussed above.

5.1.4.6   Contamination

Because the trial was single-blind, participants were aware of their allocation. One might wonder whether participants in the control group sought additional care, such as privately-funded physiotherapy or personal training, to compensate for their allocation. Many participants described seeking such additional assistance at the 12-month visit, but because the assessor was masked to allocation it was impossible to tell whether this health-seeking behaviour was a consequence of allocation, or whether it was, in fact, motivated by receiving the Take Charge session. However, the six and 12-month results showed no difference in rehabilitation contact between groups.

Aotearoa New Zealand, being a small country, meant there was a chance that contamination occurred through participants sharing their Take Charge session

booklets or discussing the intervention with their local stroke support group. However, we believe that the Take Charge session consists of more than the booklet itself, which is only a guide. Reading another person's booklet would not exert the same effect as receiving the Take Charge session, as it is the session itself that is wholly tailored toward the patient and their recovery.

Contamination could also have occurred at some of our external sites where the research clinicians were members of the local, clinical stroke or rehabilitation teams. For example, it is possible that a participant could have been treated by their research clinician in passing as one of the physiotherapists. To minimise contamination, we specifically trained two research clinicians at these sites. This ensured that if one research clinician was part of the treating team, the other would be responsible for the study visits.

Involvement in the trial would have inevitably led to change in clinical practice by the therapist-research clinicians, however great or small. Changes in the way they viewed and treated all their patients, not just the ones involved in the study, were reported by the therapist-RCs (Riley et al., 2017). This was an unavoidable, unmodifiable consequence but the study team viewed it as a positive one. Our hope is that every patient will one day benefit from the principles of Take Charge.

5.1.4.7 *Limitations with the outcome instruments chosen*
We experienced some limitations when using the chosen instruments during our home visits. These will now be explained.

Our formatting of the modified Rankin scale (mRS) was different at different imes. At the initial home visits, where instruments were completed by the RCs, the mRS was formatted in the traditional method. However, for ease of participant completion of the

6 and 12-month questionnaires, we transformed the modified Rankin scale into a structured interview approach:

1. Are you fully recovered from your stroke?

 Yes = mRS 0   No = continue

2. Are you disabled in any way by your stroke?

 No = mRS 1   Yes = continue

3. Do you need help with day-to-day activities?

 No = mRS 2   Yes = continue

4. Are you able to walk independently?

Yes = mRS 3   No = mRS 4

A score of 5 on mRS was determined from reports by proxy, who were usually the participant's carers (or nursing staff at hospital level care). When responses to the six-month questionnaire were discussed with participants over the telephone, at times they voiced uncertainty about the definition of 'disabled'. The response to the subsequent question was helpful in confirming the level of dependence, regardless of whether or not the person felt they were 'disabled'. We decided to accept subjective self-report on whether a symptom was considered disabling. For example, a quadrantanopia (partial visual defect) that prohibited a person from reading or driving could have been considered extremely disabling by one person, while another person might have barely noticed their quadrantanopia.

Our observations when using the mRS were in keeping with conclusions of a systematic review of the reliability of the mRS. As highlighted in an earlier chapter in the Methods, Quinn and colleagues found that inter-rater variability of mRS varied from 'near perfect' (weighted Kappa = 0.95) to 'poor' (Kappa = 0.25) (Quinn et al., 2009).

The majority of missing data were due to some participants being too cognitively impaired to complete the instruments. For some instruments, such as the BI and FAI, proxy responses were accepted. However, it was difficult to know how reliable proxy reports were for the subjective measures of the EQ-5D and Short Forms, and therefore, these would be left uncompleted. A surprisingly large number of people struggled with completing the visual analogue scale (VAS) of the EQ-5D because they felt unable to translate the multi-dimensional state of health into a single number. For the six-month visit, it was also impossible to ask the VAS over the telephone unless the participants had their questionnaire in front of them as this would have defeated the purpose of the VAS being a visual scale.

Further limitations with the outcome instruments became apparent when the outcomes assessor commenced the 12-month visits.

The SF-36 was felt to be insufficient at incorporating components of people's lives that contributed significantly to their quality of life, such as voluntary work, and social activities, such as outdoor recreation, card games, and mah-jong. In addition, certain conditions that reduced quality of life were not well-captured. A clear example of this was cognitive impairment. The Mental Health domain items centred on emotional health and mood, such as depression and anxiety, but overlooked the disabling impact of cognitive impairment and cognitive fatigue in people with stroke.

Participants and their families commonly reported feeling frustration due to the participants' cognitive slowing, but this was also not well-captured. Sometimes cognitive slowing was manifested as an inability to read books (because the person could not recall the plot or the characters), or in word-finding difficulty (expressive aphasia). While it might have been possible to partially capture cognitive fatigue in the questions relating to tiredness and feeling worn out, it felt as though the social and vocational

impact of cognitive impairment was not addressed adequately enough in the social functioning questions. Participants experiencing these problems also expressed frustration that the lack of questions about their cognition made them feel as though the problem was not being taken seriously.

Participants identified other problems that significantly impacted their quality of life, such as fatigue, relationship and financial problems, grief, and sleep difficulty. These symptoms were difficult to quantify within the SF-36 and the fact that our instruments did not adequately capture the severity of these symptoms was unsurprising. We had known during the planning stages of TaCAS that no instrument would have been capable of measuring every concern that afflicted the human spirit, and the concept of health-related quality of life was a difficult one. This concern was discussed with the study team, and it was felt that on balance, introducing new instruments would be too problematic, and not worth increasing the length of time of each visit. The potential benefit of measuring individual symptoms was also unclear, as the focus of the study was on quality of life overall.

The PAM was felt by the blinded outcomes assessor to be a problematic instrument. Because ample time was taken to build a holistic picture of how the participant had been faring and how they felt about their health, the assessor found that the responses that participants gave to questions in the PAM were, quite commonly, inconsistent with what the assessor already knew about the participant. Each statement was phrased in an affirmative tone, and some participants were observed to "Agree" with the statements almost without thinking. The PAM was also lacked meaningful response choices available to participants who felt that they "Agreed with the statement sometimes but not other times". Responses to similar statements within the PAM also contradicted each other. A common example was that a participant would "Disagree" with *"I am able to maintain (keep up with) lifestyle changes, like eating right and exercising"* but later "Agree"

with *"I am able to maintain lifestyle changes, like eating right and exercising, even during times of stress."*

Also, because participants were being asked to respond to statements read out by a doctor (the blinded outcomes assessor), it was suspected that there could have been responder bias towards agreeing with the statements, but this was also impossible to confirm. The PAM's limited reliability meant that it was the first instrument to be abandoned whenever a participant expressed fatigue or had other reasons to cut the final visit short.

5.1.5   Subgroup analyses

Based on the results of the subgroup analyses, one could hypothetically build a profile of what the ideal person who would benefit the most from the Take Charge session might look like. This might be a person with stroke who was female, lived alone, but had a support person.

Conclusions of this nature are risky due to the inherent nature of subgroup analyses being 'bound to turn something up', even when they are pre-specified. This is because the study was not designed to detect a difference between these subgroups, and it may have been entirely coincidental that these were found. For example, the gender difference and the living alone factor were unexpected. However, these findings are worth discussing because of the hypotheses they have generated.

TaCAS found moderate evidence for a large effect of the Take Charge session in female participants (point estimate of difference 6.4 units). By contrast, there was little effect in male participants (point estimate 0.4 units) which was not statistically significant. This finding occurred in the setting of there being fewer females (42%) than males in the

study. While it is possible that this result was due to chance, it does raise the question of whether something about the intervention itself appealed more to women. Further, all of the RCs who delivered the Take Charge session were female. This could possibly have led to easier relatability, better rapport-building, and perhaps greater trust between RCs and subjects.

The status of living alone was initially thought to go against the pre-existing evidence that having a spouse or carer who lived with a person with stroke improved outcomes. However, in this particular population (over 97% European), the status of living alone was more likely to reflect a pre-existing level of independence and ability to cope on one's own.

The masked outcomes assessor met a number of widows/widowers who were used to living alone, as well as independent women who had chosen not to marry, but who led successful, fulfilling lives. In particular, these single women valued their independence and expressed a sense of pride and desire to preserve their way of life. This spirit was in contrast to that of couples who lived together, who, to a certain extent might have been more inter-dependent and reliant upon the other person to provide motivation or support.

5.2   The Take Charge session: "How does it work?"

The previous section attempted to address the difference in treatment group effect size between MaPSS and TaCAS, which tested essentially the same intervention. What is clear from this enquiry is that the effect of Take Charge on a person with stroke likely depends upon intrinsic and extrinsic factors. Intrinsic factors include each person's own unique feelings of identity, self-worth, purpose, autonomy, mastery, and connectedness

to others. These factors have been shown to comprise a person's intrinsic psychological needs in the Self Determination Theory of human motivation (Ryan & Deci, 1985). Extrinsic factors include sociocultural and economic factors that also contribute to quality of life and barriers to recovery.

One of the most striking findings in the TaCAS statistical analysis was the discovery of a relationship between baseline AMP-C score and SF-36 PCS at 12 months. This linear relationship was only present in the control group, in which every one unit increase in the AMP-C score predicted a 1.73 unit increase in the PCS at 12 months (95% CI 0.90 to 2.56, $p < 0.001$).

This finding was surprising because the AMP-C score was a rudimentary measure which we derived based on the important concepts of SDT (see Section 3.6.11). However, the relationship supported the mechanistic idea that Take Charge worked to somehow change or augment a person's intrinsic levels of autonomy, mastery, purpose, and connectedness, so that their baseline AMP-C values no longer determined their quality of life at 12 months following stroke. For those who did not receive Take Charge, their intrinsic levels of AMP-C directly predicted their quality of life at 12 months after stroke.

In contrast, there was no relationship between baseline level of activation, randomisation, and outcomes at 12 months. It is possible that the concept of activation, though well-intentioned, distracts those who wish to test new interventions in self-management. The concept is attractive to those in health management, as 'activating patients to self-manage' is aimed at cutting health expenditure. However, modelling studies by the developers of the PAM did not show statistically significant differences in change in behaviour between two groups of people randomised to a self-management intervention and control (J. H. Hibbard et al., 2007).

In health, there has been a focus on modifying concepts such as patient activation, in relation to behavioural change and the ability to self-manage one's health, especially in the context of chronic disease. However, qualitative research has shown that the current clinical environment in which people with stroke find themselves in the first few days to weeks after stroke may be contributing to a reduction in the person's activation or self-efficacy (Brown et al., 2014; Rosewilliam et al., 2011).

Furthermore, grit psychologists have studied how gritty individuals make use of the hierarchical goal framework (Figure 5, page 110). Grit is defined as 'the passion and perseverance for the achievement of long-term goals, with the determination to overcome setbacks and failures' (Duckworth et al., 2007). It has been proposed that grit involves focusing on one superordinate, challenging goal, over a long stretch of time. On the flipside, psychologists expect individuals without a superordinate objective to approach goals with less passion, because there is no transfer of motivation from a highly-valued objective (Eskreis-Winkler et al., 2015). Motivation and likelihood of achieving a super-ordinate goal is also lower when a person does not have many options for lower-order goals to get there.

In this respect, it is possible that within neurological rehabilitation, the act of limiting a patient's chosen goals within a therapist's perception of what is 'realistic' or 'achievable' may be doing the patient a disservice. Perhaps by shedding these limitations, the Take Charge session was an intervention that built grit. To evaluate this possibility, it may be worthwhile measuring grit levels in future studies of the intervention.

5.3   Future directions

The significance of the findings of the TaCAS study was discussed in the previous section. In this final section, I will contemplate the implications of the results for clinical practice and possible considerations for implementing the Take Charge intervention. Finally, we will ponder the possibilities for future research that are indicated by these results.

5.3.1   Implications for clinical practice

Since it has been established that the effect of the Take Charge session on SF-36 PCS is statistically and clinically significant, it is important to explain the relevance of this result.

First, the result confirms that the Take Charge session is effective in this particular population of people with stroke, i.e. non-Māori, non-Pacific, mostly European, older patients, with milder stroke, compared to the population in MaPSS (M. Harwood et al., 2012). The scope of the population in which the Take Charge session has now been shown to be effective has widened significantly, and the mechanism of its effect is unlikely to be based on cultural factors alone. Rather, it is likely that the mechanism lies within the whole approach of the Take Charge session being as holistic and person-centred as possible.

Second, this intervention has been shown to be consistent at exerting its effect at the highest ICF level: participation and quality of life. Outcomes at this level are not routinely measured in clinical practice. Therefore, because quality of life is not directly assessed in clinical practice, the patient's most meaningful dimension of their function may be overlooked.

It is an uncomfortable truth that as clinicians, we choose not to measure whether what we are currently doing for people makes a meaningful difference to the long-term, most important parts of their lives. Furthermore, there are no interventions in the stroke rehabilitation literature that have effected change at this level when tested in a moderately large population of people with stroke in a randomised controlled trial. This raises two further points of note.

First, from the clinician's perspective, relying solely on traditional rehabilitative techniques with the intention of truly wanting to help the client may, in the long-term, lead to low job satisfaction and clinician burnout. It is proposed, therefore, that as an intervention that improves quality of life, the Take Charge session may also improve the work satisfaction of therapists and clinicians, if it is used to supplement therapy-based rehabilitation.

Second, because the Take Charge session exerted its effect at the highest level of functioning, *not* at a lower level related specifically to the stroke, such as impairment, the Take Charge session improved the overall quality of life despite the presence of comorbidities. In TaCAS, we gathered data about comorbidities relevant to stroke risk. Individual patient data about other comorbidities – the type, extent, or severity – were not collected because it would have been too difficult due to the heterogeneity of the data.

However, it was evident at the 12-month home visits and on review of medical records that it was common for TaCAS participants to have multiple comorbidities, some of which were not related to stroke. These included, but were not limited to: connective tissue diseases, such as rheumatoid arthritis, osteoarthritis, and polymyalgia rheumatica; chronic obstructive pulmonary disease; fractures of the hip, shoulder, or wrist; and

cancer. At times, it was evident to the outcomes assessor that comorbidities were contributing as much to a person's impairment or activity limitation as the stroke, if not more.

The result being positive in the presence of such comorbidities suggests that this particular type of intervention may be effective at improving the lives of those who are affected by other health conditions or disease. It is worth remembering that the initial WHO classification – the ICIDH – was first developed for people with rheumatological disease. In addition, the common concept of Taking Charge was first elucidated in a qualitative study of people with arthritis, chronic pain, and stroke (McPherson et al., 2004). It is paramount that future research investigates whether or not the effect of the Take Charge session translates across other health conditions.

The Take Charge session, therefore, has the potential benefit of improving the quality of life of patients with stroke <u>and</u> therapists, as well as patients affected by other conditions. This benefit can occur even in the presence of multiple comorbidities.

5.3.2   Considerations for implementation of Take Charge

There are several important things to consider if one is planning to incorporate the Take Charge session into routine clinical practice.

Firstly, where would the Take Charge session best fit in with usual community rehabilitation? In the present study, we delivered the session as a supplement to any outpatient rehabilitation that the person was receiving. We did our utmost to ensure that outpatient rehabilitation appointments were prioritised over the study visits.

However, if we are to accept the findings of the qualitative studies – namely those which showed a lack of person-centredness in current practice – then we need to wonder

whether current practice warrants changing. Further, if we are to accept the findings from Self-Determination Theory that extrinsically-motivated goals and environments that do not support autonomy, mastery, and relatedness can worsen outcomes, then the significance of this question grows.

Should we be exploring a completely different approach to every patient interaction? Instead of purely focusing on motivating the patient and trying to stimulate them to change behaviour, what if we turned our gaze inwards and tried to understand how our interactions shape their outcomes?

Previously, it was mentioned that at times, we practise with fear and avoidance of difficult truths. As clinicians, we ask closed questions that frame the answers we wish to hear. Even textbooks written by eminent rehabilitation researchers emphasise the use of predictors to best select patients 'most appropriate' for rehabilitation, to maximise the best use of limited resources, to set realistic, ascertainable goals.

The reality is that as clinicians we do not identify with the idea of using predictive tools to give hope, to lift people up in their greatest time of need, or to study ways to maximise recovery beyond that of impairment. There is an early, pre-morbid expectation that any person who has a stroke will remain limited in one way or another, and since this is our expectation, so it will be the patient's lot. Our apathy and acceptance may be the strongest predictors of poor outcomes. Our succumbing to the pressures of the system in which we practise means we no longer prioritise the needs of the individual patient in front of us.

For example, as clinicians, we blindly accept the rules used to dictate a patient's movement within the hospital's walls. A patient's freedom of mobility is governed by a cardboard traffic light 'of safety', and which is enforced by admonishing reminders to

ring the call bell for assistance, and being penned within metal bedrails. Imagine for a moment if mobility was encouraged and supported by ward staff – nurses, doctors, health care assistants – who were free and available to help. What a contrast this would be to current, didactic, inpatient ward environments. Furthermore, when even the basic freedoms of when a person can eat or when they can perform their ablutions is removed, one is compelled to ask: what autonomy is left?

When a patient needs time, someone to ask the *right questions*, someone to hear their *honest answers*, and someone to explain to them that *all predictors are only as accurate as they were in the study population on which they were based*, they do not receive this. They do not get someone in their corner, whispering encouragements to aim for the stars. Someone asking the critical questions that give the person permission to solve problems for themselves, to fight for their rights to continue living with a good quality of life. These are the intentions of Take Charge.

Instead, most patients are told not to expect a full recovery. (Multiple TaCAS participants reported being told this by health professionals and feeling as though all hope was lost.) They are told they cannot drive, which, while a legal necessity, is still a major cause of social isolation. They are told their chance of a second stroke occurring is high, but might be reduced by taking a number of tablets and by consuming less salt. They are disabled, but are told they must exercise. If they are lucky, someone might tell that they will be profoundly tired for the first few weeks to months, but not necessarily give them the skills to figure out how to manage their fatigue.

Most often, we do not mention the expected impact of stroke upon the person's work, productivity, relationships, hobbies, and ability to enjoy the things they enjoyed before the stroke. Spouses and children are expected to cope with the consequences. Hopes and fears are not routinely sought or acknowledged. What little funded services we have

deal with isolation (or the lack of an able-bodied individual living under the same roof) by bringing in a housekeeper for half an hour every two weeks.

The Take Charge session cannot fix all of these problems. It cannot come close to addressing prejudices and the limitations of low staffing. It is not a quick fix that can force a clinician to suddenly become more interested in a patient's needs.

However, what the TaCAS study has done is produce a signal. That when we practise with empathy, when we allow the environment to support autonomy, mastery, connectedness, and purposefulness, and when we provide a person with the tools to Take Charge of their own recovery, their quality of life improves. This is a signal that we cannot continue to ignore.

Furthermore, this positive effect could only have occurred because the Take Charge session was able to undo some of the negative experiences created by our well-intentioned but misguided care. Therefore, it is worth considering whether we should take a different approach to every patient interaction we have. Perhaps we should be aiming to be 'as person-centred as possible' with every patient, rather than leaving it up to an add-on, like the Take Charge session or another person, to pick up the pieces.

Another consideration is who would be the ideal person to <u>do</u> the Take Charge session? We found that our research nurses generally took up the facilitator role well, especially one nurse who had had some counselling experience. The requirements of the role were slightly more challenging to adapt to for those research clinicians who held clinical rehabilitation roles. While this was unsurprising, the effort required to change their mindset to prevent their returning to some of the paternalistic practices of traditional rehabilitation was significant. The regular contact and reminders that were required to

keep the therapist-research clinicians focused on person-centred (rather than therapy-led) goal setting was noticeable.

Simply giving the Take Charge session to community rehabilitation as a tool runs the risk of the concept quickly being lost within the practised habits of clinicians, who would then continue to do what they have done all along. Perhaps they might *believe* they had become more person-centred, but as Rosewilliam's study showed, a perceptual practice gap exists. This gap is likely to continue to grow if clinicians do not recognise or address it (Rosewilliam et al., 2011).

In the current climate, we are probably better off training people who hold the Community Stroke Advisor roles employed by the Stroke Foundation of New Zealand to facilitate the Take Charge session. The aim of their role is *'to help stroke survivors realise their full potential for recovery and wellbeing following a stroke'* and this is framed in language that is empowering. Because they are not employed within the public hospital system, their interactions with patients are less likely to be affected by the external pressures of the health system.

5.3.3   Future research

A transforming intervention

In future studies, we need to look at ways of improving the Take Charge intervention. The best way of doing this would be to invite feedback from people with stroke and their families, and to study this feedback in a qualitative manner.

Examples of questions that warrant investigating include:

- What were the parts of the Take Charge session that people most responded to?

- How important was it to have a facilitator who was ethnicity-matched, or gender-matched?

- Were there features of the session that were more important to Māori and Pasifika, and less so for Pākehā?

- If indeed, in its current iteration, the Take Charge session is much more effective in women, then how do we make it work better for men?

- How transformative is the visualisation or drawing of 'My Best Day'? Does the effect of the intervention differ if visualising and describing is used rather than drawing?

- Would patients respond better (or worse) to a booklet that was more 'professional looking', printed on glossy paper with professional illustrations rather than stick figures?

Our expectation is that the intervention will continue to evolve as researchers continue to test it in other populations.

Planned publications from this study

The study team have some ideas about publications that they wish to publish from the findings of the TaCAS study. The first publication has been submitted to the New England Journal of Medicine, and is currently awaiting review.

First, it would be wise to test the Take Charge session with a higher number of doses in each arm, to see whether the dose-response curve reaches a plateau. This will determine the optimum 'dose' of Take Charge, when a saturation point for improvement of outcomes has been reached. At the moment, the dose-response of one to two sessions is still fairly linear (see Figure 15, page 223).

Second, one of the more curious results within the TaCAS subgroup analysis was a large effect size observed in women. To test whether this effect is real, it would be worth stratifying future study populations by gender, and perhaps gender-matching (or mismatching) the facilitators of the Take Charge session, to confirm whether or not gender influences the effect of Take Charge.

Third, translated versions of the Take Charge session need to be tested in other ethnic groups. This is required because the cultural contexts of those ethnicities with whom we have not thoroughly tested the Take Charge intervention are different to those of Māori, Pasifika, and Europeans. Yet, the key health concerns among Asian and Indian populations in New Zealand are cardiovascular disease (including stroke) and diabetes. The population of Asian peoples in New Zealand is projected to increase by 22% in the next 20 years (Statistics New Zealand, 2017). Implementing the Take Charge session throughout the country without attempting to modify it to be culturally appropriate for these ethnic groups will likely affect the uptake of the intervention by these patients, which may produce variable results.

Fourth, because the effect of Take Charge was so significant in Māori and Pasifika people with stroke, it is imperative that the intervention is tested in Māori and Pasifika who are affected by other chronic health conditions. These include Type II diabetes, obesity, and mental health conditions.

Fifth, Take Charge should be tested in all patients with chronic conditions, such as Parkinson disease, multiple sclerosis, and cancer. Currently, a feasibility study is being conducted testing the Take Charge session in patients with chronic obstructive pulmonary disease (W. Levack, 2017).

Sixth, the Take Charge intervention has only been evaluated within the context of Aotearoa New Zealand's publicly-funded health system. Acute hospital care, early supported discharge, and community rehabilitation are all free to the patient. It would be important to test the Take Charge session within other health systems, which may have different community rehabilitation service provisions for people after stroke.

Finally, the TaCAS study has highlighted the need for better measurement tools for rehabilitation outcomes. Time could be well-spent devising a tool for measuring the personal, emotional, and social impact of cognitive impairment. The input of patient focus groups and neuropsychologists would be valuable to begin this process. The AMP-C was a previously untested instrument, yet produced interesting results supporting the mechanistic action of the Take Charge intervention. One could consider devising a more refined instrument for measuring the AMP-C, incorporating Deci and Ryan's validated measures of autonomy and perhaps Duckworth's Grit Scale. Subsequently, it could be validated within the general population as well as in people with stroke and other chronic illness.

If this instrument was successful at measuring how well an individual's intrinsic psychological needs are met, it could be the start of other creative, novel interventions emerging. Further interventions targeting change at this level would build resilient, happier individuals. The ultimate goal is that Take Charge will lead to communities of people with stroke, and others living with chronic illness, experiencing better quality of life.

6 Conclusion

The Taking Charge After Stroke study showed that a novel, person-centred intervention, the Take Charge session, was effective at improving quality of life in people with stroke. This effect was maintained at one year after stroke, and was supported by better outcomes at the level of participation. Furthermore, the session had a positive dose effect – outcomes after two sessions were better than those after one.

Combined with the results of the Māori and Pacific Stroke study, the meta-analysis results provide evidence for a number needed to treat of about eight for one person to be independent at one year after stroke. This is comparable to the effect size of intravenous thrombectomy given within three hours of acute stroke. The Take Charge session, however, is a simple and safe intervention, appropriate for most people after stroke.

The Take Charge session should be implemented as a community-based intervention for all New Zealanders after stroke. It should be tested in populations of other ethnicities, with other health conditions, and within other health systems.

7 References

Albers, G. W., Lansberg, M. G., Kemp, S., Tsai, J. P., Lavori, P., Christensen, S., … Marks, M. P. (2017). A multicenter randomized controlled trial of endovascular therapy following imaging evaluation for ischemic stroke (DEFUSE 3). *International Journal of Stroke : Official Journal of the International Stroke Society*, *12*(8), 896–905. https://doi.org/10.1177/1747493017701147

Alim, M., Lindley, R., Felix, C., Gandhi, D. B. C., Verma, S. J., Tugnawat, D. K., … Pandian, J. D. (2016). Family-led rehabilitation after stroke in India: the ATTEND trial, study protocol for a randomized controlled trial. *Trials*, *17*(1), 13. https://doi.org/10.1186/s13063-015-1129-8

Allen, K., Hazelett, S., Jarjoura, D., Hua, K., Wright, K., Weinhardt, J., & Kropp, D. (2009). A Randomized Trial Testing the Superiority of a Postdischarge Care Management Model for Stroke Survivors. *Journal of Stroke and Cerebrovascular Diseases*, *18*, 443–452. https://doi.org/10.1016/j.jstrokecerebrovasdis.2009.02.002

Allen, K. R., Hazelett, S., Jarjoura, D., Wickstrom, G. C., Hua, K., Weinhardt, J., & Wright, K. (2002). Effectiveness of a postdischarge care management model for stroke and transient ischemic attack: A randomized trial. *Journal of Stroke and Cerebrovascular Diseases*, (11), 88–98. https://doi.org/10.1053/jscd.2002.127106

Amp up definition and meaning | Collins English Dictionary. (2018). Retrieved October 12, 2018, from https://www.collinsdictionary.com/dictionary/english/amp-up

Anderson, C., Laubscher, S., & Burns, R. (1996). Validation of the Short Form 36 (SF-36) health survey questionnaire among stroke patients. *Stroke; a Journal of Cerebral Circulation*, *27*(10), 1812–1816. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/8841336

Ao, B. J. Te, Brown, P. M., Feigin, V. L., & Anderson, C. S. (2012). Are Stroke Units Cost Effective? Evidence from a New Zealand Stroke Incidence and Population-Based Study. *International Journal of Stroke*, *7*(8), 623–630. https://doi.org/10.1111/j.1747-

4949.2011.00632.x

Appelros, P. (2007). Characteristics of the Frenchay Activities Index one year after a stroke: A population-based study. *Disability and Rehabilitation*, *29*(10), 785–790. https://doi.org/10.1080/09638280600919715

Arroll, B., Goodyear-Smith, F., Crengle, S., Gunn, J., Kerse, N., Fishman, T., … Hatcher, S. (2010). Validation of PHQ-2 and PHQ-9 to screen for major depression in the primary care population. *Annals of Family Medicine*, *8*(4), 348–353. https://doi.org/10.1370/afm.1139

Auerbach, S. M. (2001). Do Patients Want Control over their Own Health Care? A Review of Measures, Findings, and Research Issues. *Journal of Health Psychology*, *6*(2), 191–203. https://doi.org/10.1177/135910530100600208

Bandura, A. (1997). *Self-Efficacy The Exercise of Control* (10th ed.). W H Freeman and Company.

Barber, P. A., Liu, Q., Brew, S., McGuinness, B., Hope, A., Moriarty, M., … Tse, D. (2015). Endovascular clot retrieval for acute ischaemic stroke: The Auckland City Hospital experience. *New Zealand Medical Journal*, *128*(1423), 57–62.

Baskett, J., & McNaughton, H. K. (2003). *Life after stroke: New Zealand guideline for management of stroke*. Wellington, New Zealand.

Berkhemer, O. A., Fransen, P. S. S., Beumer, D., van den Berg, L. A., Lingsma, H. F., Yoo, A. J., … Dippel, D. W. J. (2015). A Randomized Trial of Intraarterial Treatment for Acute Ischemic Stroke. *New England Journal of Medicine*, *372*(1), 11–20. https://doi.org/10.1056/NEJMoa1411587

Bhatia, R., Hill, M. D., Shobha, N., Menon, B., Bal, S., Kochar, P., … Demchuk, A. M. (2010). Low Rates of Acute Recanalization With Intravenous Recombinant Tissue Plasminogen Activator in Ischemic Stroke. *Stroke*, *41*(10), 2254–2258. https://doi.org/10.1161/STROKEAHA.110.592535

Bright, F. A. S., Boland, P., Rutherford, S. J., Kayes, N. M., & McPherson, K. M. (2012). Implementing a client-centred approach in rehabilitation: an autoethnography.

Disability and Rehabilitation, *34*(12), 997–1004.

https://doi.org/10.3109/09638288.2011.629712

Broderick, J. P., Palesch, Y. Y., Demchuk, A. M., Yeatts, S. D., Khatri, P., Hill, M. D., … Tomsick, T. A. (2013). Endovascular Therapy after Intravenous t-PA versus t-PA Alone for Stroke. *New England Journal of Medicine*, *368*(10), 893–903.

https://doi.org/10.1056/NEJMoa1214300

Brook, R. H., Ware, J. E., Rogers, W. H., Keeler, E. B., Davies, A. R., Sherbourne, C. D., … Newhouse, J. P. (1984). The Effect of Coinsurance on the Health of Adults. Retrieved from https://www.rand.org/pubs/reports/R3055.html

Brott, T., Adams, H. P., Olinger, C. P., Marler, J. R., Barsan, W. G., Biller, J., … Hertzberg, V. (1989). Measurements of acute cerebral infarction: a clinical examination scale. *Stroke*, *20*(7), 864–870. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/2749846

Brown, M., Levack, W., McPherson, K. M., Dean, S. G., Reed, K., Weatherall, M., & Taylor, W. J. (2014). Survival, momentum, and things that make me "me": patients' perceptions of goal setting after stroke. *Disability and Rehabilitation*, *36*(12), 1020–1026. https://doi.org/10.3109/09638288.2013.825653

Buchan, A., Barber, P., Newcommon, N., Karbalai, H., Demchuk, A., Hoyte, K., … Feasby, T. (2000). Effectiveness of t-PA in acute ischemic stroke: outcome relates to appropriateness. *Neurology*, *54*, 679–684.

Cadilhac, D. A., Carter, R., Thrift, A. G., & Dewey, H. M. (2009). Estimating the long-term costs of ischemic and hemorrhagic stroke for Australia: new evidence derived from the North East Melbourne Stroke Incidence Study (NEMESIS). *Stroke; a Journal of Cerebral Circulation*, *40*(3), 915–921.

https://doi.org/10.1161/STROKEAHA.108.526905

Campbell, B. C. V., Mitchell, P. J., Kleinig, T. J., Dewey, H. M., Churilov, L., Yassi, N., … Davis, S. M. (2015). Endovascular Therapy for Ischemic Stroke with Perfusion-Imaging Selection. *New England Journal of Medicine*, *372*(11), 1009–1018.

https://doi.org/10.1056/NEJMoa1414792

Catalano, T., Dickson, P., Kendall, E., Kuipers, K., & Posner, N. (2003). The perceived benefits of the chronic disease self-management program among participants with stroke: A qualitative study. *Australian Journal of Primary Health*, *9*. https://doi.org/10.1071/PY03028

Chen, Z. M. C. (Chinese A. S. T. C. G. (1997). CAST: Randomised placebo-controlled trial of early aspirin use in 20,000 patients with acute ischaemic stroke. *Lancet*, *349*(9066), 1641–1649. https://doi.org/10.1016/S0140-6736(97)04010-5

Ciccone, A., Valvassori, L., Nichelatti, M., Sgoifo, A., Ponzio, M., Sterzi, R., & Boccardi, E. (2013). Endovascular Treatment for Acute Ischemic Stroke. *New England Journal of Medicine*, *368*(10), 904–913. https://doi.org/10.1056/NEJMoa1213701

Coast, J., Peters, T. J., Richards, S. H., & Gunnell, D. J. (1998). Use of the EuroQoL among elderly acute care patients. *Quality of Life Research : An International Journal of Quality of Life Aspects of Treatment, Care and Rehabilitation*, *7*(1), 1–10. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/9481146

Colantonio, A., Kasl, S. V., Ostfeld, A. M., & Berkman, L. F. (1993). Psychosocial Predictors of Stroke Outcomes in an Elderly Population. *Journal of Gerontology*, *48*(5), S261–S268. https://doi.org/10.1093/geronj/48.5.S261

Collin, C., Wade, D. T., Davies, S., & Horne, V. (1988). The Barthel ADL Index: A reliability study. *International Disability Studies*, *10*(2), 61–63. https://doi.org/10.3109/09638288809164103

Creer, T. L., & Burns, K. L. (1979). Self-management training for children with chronic bronchial asthma. *Psychotherapy and Psychosomatics*, *32*(1–4), 270–278. https://doi.org/10.1159/000287396

Csikszentmihalyi, M. (2014). *Flow and the Foundations of Positive Psychology: The Collected Works of Mihaly Csikszentmihalyi*. Springer Science+Business Media. https://doi.org/10.1007/978-94-017-9088-8

Damush, T. M., Ofner, S., Yu, Z., Plue, L., Nicholas, G., & Williams, L. S. (2011). Implementation of a stroke self-management program: A randomized controlled

pilot study of veterans with stroke: A randomized controlled pilot study of veterans with stroke. *Translational Behavioral Medicine*, (1), 561–572. https://doi.org/10.1007/s13142-011-0070-y

de Haan, R. J. (2002). Measuring Quality of Life After Stroke Using the SF-36. *Stroke*, *33*(5), 1176–1177. https://doi.org/10.1161/01.STR.0000015223.98452.97

Deci, E. L., & Ryan, R. M. (2000). *The "What" and "Why" of Goal Pursuits: Human Needs and the Self-Determination of. Psychological Inquiry* (Vol. 11). Retrieved from https://www-jstor-org.helicon.vuw.ac.nz/stable/pdf/1449618.pdf

DeJong, G., Horn, S. D., Conroy, B., Nichols, D., & Healton, E. B. (2005). Opening the black box of post-stroke rehabilitation: stroke rehabilitation patients, processes, and outcomes. *Arch Phys Med Rehabil*, *86*(12 Suppl 2), S1–S7. https://doi.org/S0003-9993(05)01259-1 [pii]\r10.1016/j.apmr.2005.09.003

Doran GT, Miller AF, C. J. (1981). There's a S.M.A.R.T. way to write management's goals and objectives. *Management Review*, *70*(11), 35.

Dromerick, A. W., Edwards, D. F., & Diringer, M. N. (2003). Sensitivity to changes in disability after stroke: a comparison of four scales useful in clinical trials. *Journal of Rehabilitation Research and Development*, *40*(1), 1–8. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/15150715

Duckworth, A. L., Peterson, C., Matthews, M. D., & Kelly, D. R. (2007). Grit: Perseverance and Passion for Long-Term Goals. *Journal of Personality and Social Psychology*, *92*(6), 1087–1101. https://doi.org/10.1037/0022-3514.92.6.1087

Duffy, L., Gajree, S., Langhorne, P., Stott, D. J., & Quinn, T. J. (2013). Reliability (Inter-rater Agreement) of the Barthel Index for Assessment of Stroke Survivors. *Stroke*, *44*(2), 462–468. https://doi.org/10.1161/STROKEAHA.112.678615

Duncan, P., Jorgensen, H. J., & Wade, D. T. (2000). Outcome Measures in Acute Stroke Trials. *Stroke*, *31*, 1429–1438.

Duncan, P W, Samsa, G. P., Weinberger, M., Goldstein, L. B., Bonito, A., Witter, D. M., … Matchar, D. (1997). Health status of individuals with mild stroke. *Stroke*, *28*(4), 740–

745. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/9099189

Duncan, Pamela W, Zorowitz, R., Bates, B., Choi, J. Y., Glasberg, J. J., Graham, G. D., … Reker, D. (2005). *Management of Adult Stroke Rehabilitation Care: a clinical practice guideline. Stroke; a journal of cerebral circulation* (Vol. 36). https://doi.org/10.1161/01.STR.0000180861.54180.FF

Ellis, G., Mant, J., Langhorne, P., Dennis, M., & Winner, S. (2010). Stroke liaison workers for stroke patients and carers: an individual patient data meta-analysis. *The Cochrane Database of Systematic Reviews*, (5), CD005066. https://doi.org/10.1002/14651858.CD005066.pub2

Emberson, J., Lees, K. R., Lyden, P., Blackwell, L., Albers, G., Bluhmki, E., … Stroke Thrombolysis Trialists' Collaborative Group. (2014). Effect of treatment delay, age, and stroke severity on the effects of intravenous thrombolysis with alteplase for acute ischaemic stroke: a meta-analysis of individual patient data from randomised trials. *Lancet (London, England)*, *384*(9958), 1929–1935. https://doi.org/10.1016/S0140-6736(14)60584-5

Eskreis-Winkler, L., Gross, J. J., & Duckworth, A. L. (2015). Grit: Sustained Self-Regulation in the Service of Superordinate Goals. In *Handbook of Self-Regulation: Research, Theory, and Applications*. New York: Guilford.

Facts about stroke in New Zealand. (n.d.). Retrieved from https://www.stroke.org.nz/facts-and-faqs

Facts and fallacies | Stroke Foundation of New Zealand. (n.d.). Retrieved July 15, 2016, from http://www.stroke.org.nz/stroke-facts-and-fallacies

Feigin, V. L., Forouzanfar, M. H., Krishnamurthi, R., Mensah, G. A., Connor, M., Bennett, D. A., … Murray, C. (2014). Global and regional burden of stroke during 1990–2010: findings from the Global Burden of Disease Study 2010. *The Lancet*, *383*(9913), 245–255. https://doi.org/10.1016/S0140-6736(13)61953-4

Feigin, V. L., Krishnamurthi, R. V, Barker-Collo, S., McPherson, K. M., Barber, P. A., Parag, V., … Bonita, R. (2015). 30-Year trends in stroke rates and outcome in

Auckland, New Zealand (1981-2012): A multi-ethnic population-based series of studies. *PLoS ONE*, *10*(8). https://doi.org/10.1371/journal.pone.0134609

Feigin, V. L., Krishnamurthi, R. V, Parmar, P., Norrving, B., Mensah, G. A., Bennett, D. A., … GBD 2013 Stroke Panel Experts Group. (2015). Update on the Global Burden of Ischemic and Hemorrhagic Stroke in 1990-2013: The GBD 2013 Study. *Neuroepidemiology*, *45*(3), 161–176. https://doi.org/10.1159/000441085

Feigin, V. L., Roth, G. A., Naghavi, M., Parmar, P., Krishnamurthi, R., Chugh, S., … Global Burden of Diseases, Injuries and Risk Factors Study 2013 and Stroke Experts Writing Group. (2016). Global burden of stroke and risk factors in 188 countries, during 1990-2013: a systematic analysis for the Global Burden of Disease Study 2013. *The Lancet. Neurology*, *15*(9), 913–924. https://doi.org/10.1016/S1474-4422(16)30073-4

Frieling, M. A., Davis, W. R., & Chiang, G. (2013). The SF-36v2 and SF-12v2 health surveys in New Zealand: norms, scoring coefficients and cross-country comparisons. *Australian and New Zealand Journal of Public Health*, *37*(1), 24–31. https://doi.org/10.1111/1753-6405.12006

Fryer, C., Luker, J., McDonnell, M., & Hillier, S. (2016). Self management programmes for quality of life in people with stroke (Review). *Cochrane Library*, (8). https://doi.org/10.1002/14651858.CD010442.pub2.www.cochranelibrary.com

Fu, V. W. Y., Weatherall, M., & McNaughton, H. (2017). The Taking Charge After Stroke (TaCAS) study protocol: a multicentre, investigator-blinded, randomised controlled trial comparing the effect of a single Take Charge session, two Take Charge sessions and control intervention on health-related quality of life 12 months after stroke for non-Māori, non-Pacific adult New Zealanders discharged to community living. *BMJ Open*, *7*(5), e016512. https://doi.org/10.1136/bmjopen-2017-016512

Gandek, B., Ware, J. E., Aaronson, N. K., Apolone, G., Bjorner, J. B., Brazier, J. E., … Sullivan, M. (1998). Cross-validation of item selection and scoring for the SF-12 Health Survey in nine countries: Results from the IQOLA Project. *Journal of Clinical*

Epidemiology. https://doi.org/10.1016/S0895-4356(98)00109-7

Ganesalingam, J., Pizzo, E., Morris, S., Sunderland, T., Ames, D., & Lobotesis, K. (2015).
Cost-Utility Analysis of Mechanical Thrombectomy Using Stent Retrievers in
Acute Ischemic Stroke. *Stroke*, *46*(9), 2591–2598.
https://doi.org/10.1161/STROKEAHA.115.009396

Goyal, M., Demchuk, A. M., Menon, B. K., Eesa, M., Rempel, J. L., Thornton, J., … Hill,
M. D. (2015). Randomized Assessment of Rapid Endovascular Treatment of
Ischemic Stroke. *New England Journal of Medicine*, *372*(11), 1019–1030.
https://doi.org/10.1056/NEJMoa1414905

Hackett, M. L., & Pickles, K. (2014). Part I: Frequency of Depression after Stroke: An
Updated Systematic Review and Meta-Analysis of Observational Studies.
International Journal of Stroke, *9*(8), 1017–1025. https://doi.org/10.1111/ijs.12357

Hancock, F. (2018). Examining racism in NZ's health system. Retrieved October 23, 2018,
from https://www.newsroom.co.nz/2018/10/14/273494/maori-health-under-tribunal-
spotlight

Harris, P. A., Taylor, R., & Thielke, R. (2009). Research electronic data capture (REDCap)
- A metadata-driven methodology and workflow process for providing translational
research informatics support. *Journal of Biomedical Informatics*, *42*(2), 377–381.

Harwood, M., Weatherall, M., Talemaitoga, a., Barber, P. a., Gommans, J., Taylor, W., …
McNaughton, H. (2012). Taking charge after stroke: promoting self-directed
rehabilitation to improve quality of life - a randomized controlled trial. *Clinical
Rehabilitation*, *26*(6), 493–501. https://doi.org/10.1177/0269215511426017

Harwood, Matire. (2010). Rehabilitation and indigenous peoples: the Māori experience.
Disability and Rehabilitation, *32*(12), 972–977.
https://doi.org/10.3109/09638281003775378

Hibbard, J., & Gilburt, H. (2014). *Supporting people to manage their health: An introduction to
patient activation*. London: The King's Fund.

Hibbard, J. H., Mahoney, E. R., Stock, R., & Tusler, M. (2007). Do increases in patient

activation result in improved self-management behaviors? *Health Services Research*, *42*(4), 1443–1463. https://doi.org/10.1111/j.1475-6773.2006.00669.x

Hibbard, J. H., Mahoney, E. R., Stockard, J., & Tusler, M. (2005). Development and testing of a short form of the patient activation measure. *Health Services Research*, *40*(6 Pt 1), 1918–1930. https://doi.org/10.1111/j.1475-6773.2005.00438.x

Hibbard, J. H., Stockard, J., Mahoney, E. R., & Tusler, M. (2004). Development of the Patient Activation Measure (PAM): conceptualizing and measuring activation in patients and consumers. *Health Services Research*, *39*(4 Pt 1), 1005–1026. https://doi.org/10.1111/j.1475-6773.2004.00269.x

Hobart, J C, Lamping, D. L., Freeman, J. A., Langdon, D. W., McLellan, D. L., Greenwood, R. J., & Thompson, A. J. (2001). Evidence-based measurement: which disability scale for neurologic rehabilitation? *Neurology*, *57*(4), 639–644. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/11524472

Hobart, Jeremy C, Williams, L. S., Moran, K., & Thompson, A. J. (2002). Quality of life measurement after stroke: uses and abuses of the SF-36. *Stroke*, *33*(5), 1348–1356. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/11988614

Holbrook, M., & Skilbeck, C. (1983). An activities index for use with stroke patients. *Age and Ageing*, *12*(2), 166–170. https://doi.org/10.1093/ageing/12.2.166

Howard, G., & Goff, D. C. (2012). Population shifts and the future of stroke: forecasts of the future burden of stroke. *Annals of the New York Academy of Sciences*, *1268*, 14–20. https://doi.org/10.1111/j.1749-6632.2012.06665.x

Hsieh, Y.-W., Wang, C.-H., Wu, S.-C., Chen, P.-C., Sheu, C.-F., & Hsieh, C.-L. (2007). Establishing the Minimal Clinically Important Difference of the Barthel Index in Stroke Patients. *Neurorehabilitation and Neural Repair*, *21*(3), 233–238. https://doi.org/10.1177/1545968306294729

Hussain, M., Moussavi, M., Korya, D., Mehta, S., Brar, J., Chahal, H., … Kirmani, J. F. (2016). Systematic Review and Pooled Analyses of Recent Neurointerventional Randomized Controlled Trials: Setting a New Standard of Care for Acute Ischemic

Stroke Treatment after 20 Years. *Interventional Neurology*, 5(1–2), 39–50. https://doi.org/10.1159/000442355

ICH Expert Working Group. (1996). *INTERNATIONAL CONFERENCE ON HARMONISATION OF TECHNICAL REQUIREMENTS FOR REGISTRATION OF PHARMACEUTICALS FOR HUMAN USE ICH HARMONISED TRIPARTITE GUIDELINE GUIDELINE FOR GOOD CLINICAL PRACTICE E6(R1)*. Retrieved from https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R1_Guideline.pdf

Insignia Health. (2018). Research Studies. Retrieved from https://www.insigniahealth.com/research/archive/

International Stroke Trial Collaborative Group. (1997). The International Stroke Trial (IST): a randomised trial of aspirin, subcutaneous heparin, both, or neither among 19435 patients with acute ischaemic stroke. International Stroke Trial Collaborative Group. *Lancet (London, England)*, *349*(9065), 1569–1581. https://doi.org/10.1016/S0140-6736(97)04011-7

IST-3 collaborative group, Sandercock, P., Wardlaw, J. M., Lindley, R. I., Dennis, M., Cohen, G., … Arauz, A. (2012). The benefits and harms of intravenous thrombolysis with recombinant tissue plasminogen activator within 6 h of acute ischaemic stroke (the third international stroke trial [IST-3]): a randomised controlled trial. *Lancet (London, England)*, *379*(9834), 2352–2363. https://doi.org/10.1016/S0140-6736(12)60768-5

Janssen, M. F., Pickard, A. S., Golicki, D., Gudex, C., Niewada, M., Scalone, L., … Busschbach, J. (2013). Measurement properties of the EQ-5D-5L compared to the EQ-5D-3L across eight patient groups: a multi-country study. *Quality of Life Research*, *22*(7), 1717–1727. https://doi.org/10.1007/s11136-012-0322-4

Jenkinson, C., Wright, L., & Coulter, A. (1994). Criterion validity and reliability of the SF-36 in a population sample. *Quality of Life Research : An International Journal of Quality*

of Life Aspects of Treatment, Care and Rehabilitation, 3(1), 7–12. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/8142947

Jones, F., Partridge, C., & Reid, F. (2008). The Stroke Self-Efficacy Questionnaire: Measuring individual confidence in functional performance after stroke. Journal of Clinical Nursing, 17(7B), 244–252. https://doi.org/10.1111/j.1365-2702.2008.02333.x

Jørgensen, H. S., Nakayama, H., Raaschou, H. O., Vive-Larsen, J., St¢ier, M., Olsen, T. S., & Jcrgensen, H. S. (1995). Outcome and Time Course of Recovery in Stroke. Part II: Time Course of Recovery. The Copenhagen Stroke Study. Archives of physical medicine and rehabilitation (Vol. 76). Retrieved from https://www.archives-pmr.org/article/S0003-9993(95)80568-0/pdf

Joshi, P; Wong, L; Weatherall, M; Lanford, J; Fu, V; McNaughton, H. (2015). A Comparison of Stroke Outcomes in Wellington, New Zealand, between 1997 and 2013. Jacobs Journal of Physical Rehabilitation Medicine, 1(2), 008.

Jovin, T. G., Chamorro, A., Cobo, E., De Miquel, M. A., Molina, C. A., Rovira, A., … Dávalos, A. (2015). Thrombectomy within 8 Hours after Symptom Onset in Ischemic Stroke for the REVASCAT Trial Investigators*. N Engl J Med, 372, 2296–2306. https://doi.org/10.1056/NEJMoa1503780

Kalra, L. (1994). The influence of stroke unit rehabilitation on functional recovery from stroke L Kalra Stroke 1994;25;821-825. Stroke, 25, 821–825. Retrieved from http://stroke.ahajournals.org/content/strokeaha/25/4/821.full.pdf

Keith, R. A., Granger, C. V, Hamilton, B. B., & Sherwin, F. S. (1987). The functional independence measure: a new tool for rehabilitation. Advances in Clinical Rehabilitation, 1, 6–18. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/3503663

Kendall, E., Catalano, T., Kuipers, P., Posner, N., Buys, N., & Charker, J. (2007). Recovery following stroke: the role of self-management education. Social Science & Medicine (1982), 64(3), 735–746. https://doi.org/10.1016/j.socscimed.2006.09.012

Kidwell, C. S., Jahan, R., Gornbein, J., Alger, J. R., Nenov, V., Ajani, Z., … Saver, J. L. (2013). A Trial of Imaging Selection and Endovascular Treatment for Ischemic

Stroke. *New England Journal of Medicine*, *368*(10), 914–923.

https://doi.org/10.1056/NEJMoa1212793

Krishnamurthi, R. V, Barker-Collo, S., Parag, V., Parmar, P., Witt, E., Jones, A., … Feigin,

V. L. (2017). Stroke Incidence by Major Pathological Type and Ischemic Subtypes in

the Auckland Regional Community Stroke Studies. *Stroke*. Retrieved from

http://stroke.ahajournals.org/content/early/2017/12/05/STROKEAHA.117.019358.abst

ract

Krishnamurthi, R. V, Feigin, V. L., Forouzanfar, M. H., Mensah, G. A., Connor, M.,

Bennett, D. A., … GBD Stroke Experts Group. (2013). Global and regional burden of

first-ever ischaemic and haemorrhagic stroke during 1990–2010: findings from the

Global Burden of Disease Study 2010. *The Lancet Global Health*, *1*(5), e259–e281.

https://doi.org/10.1016/S2214-109X(13)70089-5

Kruglanski, A. W., Pierro, A., & Sheveland, A. (2011). How many roads lead to Rome?

Equifinality set-size and commitment to goals and means. *European Journal of Social

Psychology*, *41*(3), 344–352. https://doi.org/10.1002/ejsp.780

Kuhl, J., & Fuhrmann, A. (1998). Decomposing self-regulation and self-control. In J.

Heckhausen & C. Dweck (Eds.), *Motivation and self-regulation across the life-span* (pp.

15–49). New York: Cambridge University Press.

Kunz, W. G., Hunink, M. G. M., Sommer, W. H., Beyer, S. E., Meinel, F. G., Dorn, F., …

Thierfelder, K. M. (2016). Cost-Effectiveness of Endovascular Stroke Therapy.

Stroke, *47*(11), 2797–2804. https://doi.org/10.1161/STROKEAHA.116.014147

Kwakkel, G., Veerbeek, J. M., Harmeling-Van Der Wel, B. C., Van Wegen, E., & Kollen,

B. J. (2011). Diagnostic accuracy of the barthel index for measuring activities of daily

living outcome after ischemic hemispheric stroke: Does early poststroke timing of

assessment matter? *Stroke*, *42*(2), 342–346.

https://doi.org/10.1161/STROKEAHA.110.599035

Lavsa, S. M., Holzworth, A., & Ansani, N. T. (2011). Selection of a validated scale for

measuring medication adherence. *Journal of the American Pharmacists Association*,

51(1), 90–94. https://doi.org/10.1331/JAPhA.2011.09154

Law, M., Baptiste, S., McColl, M., Opzoomer, A., Polatajko, H., & Pollock, N. (1990). The Canadian Occupational Performance Measure: An Outcome Measure for Occupational Therapy. *Canadian Journal of Occupational Therapy*, *57*(2), 82–87. https://doi.org/10.1177/000841749005700207

Lee, J. Y., Ready, E. A., Davis, E. N., & Doyle, P. C. (2017). Purposefulness as a critical factor in functioning, disability and health. *Clinical Rehabilitation*, *31*(8), 1005–1018. https://doi.org/10.1177/0269215516672274

Lennon, S., McKenna, S., & Jones, F. (2013). Self-management programmes for people post stroke: A systematic review. *Clinical Rehabilitation*, *27*(10), 867–878. https://doi.org/10.1177/0269215513481045

Levack, W. (2017). Can a "take charge" intervention reduce incidence of repeat acute exacerbation of chronic obstructive pulmonary disease? A feasibility study. ANZCTR ACTRN12617000952347p. Retrieved November 15, 2018, from https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=373172&isReview=true

Levack, W. M. M., Weatherall, M., Hay-Smith, E. J. C., Dean, S. G., McPherson, K., & Siegert, R. J. (2015). Goal setting and strategies to enhance goal pursuit for adults with acquired disability participating in rehabilitation. *The Cochrane Database of Systematic Reviews*, (7), CD009727. https://doi.org/10.1002/14651858.CD009727.pub2

Lindley, R. I., Anderson, C. S., Billot, L., Forster, A., Hackett, M. L., Harvey, L. A., … ATTEND Collaborative Group, T. (2017). Family-led rehabilitation after stroke in India (ATTEND): a randomised controlled trial. *The Lancet*, *390*, 588–599. https://doi.org/10.1016/S0140-6736(17)31447-2

Lloyd, A., Roberts, A. R., & Freeman, J. A. (2014). "Finding a Balance" in Involving Patients in Goal Setting Early After Stroke: A Physiotherapy Perspective. *Physiotherapy Research International*, *19*(3), 147–157. https://doi.org/10.1002/pri.1575

Lorig, K., Chastain, R. L., Ung, E., Shoor, S., & Holman, H. R. (1989). Development and

evaluation of a scale to measure perceived self-efficacy in people with arthritis. *Arthritis & Rheumatism.* https://doi.org/10.1002/anr.1780320107

Lorig, K R, Ritter, P., Stewart, A. L., Sobel, D. S., Brown, B. W., Bandura, A., … Holman, H. R. (2001). Chronic disease self-management program: 2-year health status and health care utilization outcomes. *Medical Care*, *39*(11), 1217–1223. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/11606875

Lorig, K R, Sobel, D. S., Stewart, A. L., Brown, B. W., Bandura, A., Ritter, P., … Holman, H. R. (1999). Evidence suggesting that a chronic disease self-management program can improve health status while reducing hospitalization: a randomized trial. *Medical Care*, *37*(1), 5–14. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/10413387

Lorig, Kate R, & Holman, H. R. (2003). *Self-Management Education: History, Definition, Outcomes, and Mechanisms. Ann Behav Med* (Vol. 26). Retrieved from https://link-springer-com.helicon.vuw.ac.nz/content/pdf/10.1207%2FS15324796ABM2601_01.pdf

Lu, W.-S., Chen, C. C., Huang, S.-L., & Hsieh, C.-L. (2012). Smallest Real Difference of 2 Instrumental Activities of Daily Living Measures in Patients With Chronic Stroke. *Archives of Physical Medicine and Rehabilitation*, *93*(6), 1097–1100. https://doi.org/10.1016/j.apmr.2012.01.015

Lyons, R. A., Perry, H. M., & Littlepage, B. N. (1994). Evidence for the validity of the Short-form 36 Questionnaire (SF-36) in an elderly population. *Age and Ageing*, *23*(3), 182–184. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/8085500

Mahoney, F., & Barthel, D. (1965). Functional Evaluation: the Barthel Index: A simple index of independence useful in scoring improvement in the rehabilitation of the chronically ill. *Maryland State Medical Journal*, *14*, 61–65. https://doi.org/10.1016/S0140-6736(10)62108-3

Mant, J., Carter, J., Wade, D. T., & Winner, S. (2000). Family support for stroke: a randomised controlled trial. *Lancet (London, England)*, *356*(9232), 808–813. https://doi.org/10.1016/S0140-6736(00)02655-6

Maruish, M. E. (2011). *User's manual for the SF-36v2 Health Survey* (3rd ed.). Lincoln, RI: QualityMetric Incorporated.

McNaughton, H., Feigin, V., Kerse, N., Alan Barber, P., Weatherall, M., Bennett, D., … Anderson, C. (2011). Ethnicity and functional outcome after stroke. *Stroke*, *42*(4), 960–964. https://doi.org/10.1161/STROKEAHA.110.605139

Mcnaughton, H., McRae, A., Green, G., Abernethy, G., & Gommans, J. (2014). Stroke rehabilitation services in New Zealand: a survey of service configuration, capacity and guideline adherence. *Journal of the New Zealand Medical Association NZMJ*, *127*(127), 10–19. Retrieved from http://www.nzma.org.nz/journal/read-the-journal/all-issues/2010-2019/2014/vol-127-no-1402/6288

McNaughton, H., McRae, A., Green, G., Abernethy, G., & Gommans, J. (2014). Stroke rehabilitation services in New Zealand: a survey of service configuration, capacity and guideline adherence. *The New Zealand Medical Journal*, *127*(1402), 10–19. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/25228417

McNaughton, H., Weatherall, M., McPherson, K., Taylor, W., & Harwood, M. (2002). The comparability of community outcomes for European and non-European survivors of stroke in New Zealand. *New Zealand Medical Journal*, *115*(1149), 98–100.

McPherson, K. M., Brander, P., Taylor, W. J., & McNaughton, H. K. (2004). Consequences of stroke, arthritis and chronic pain--are there important similarities? *Disability and Rehabilitation*, *26*(16), 988–999. https://doi.org/10.1080/09638280410001702414

Ministry of Health Manatu Hauora. (n.d.). Income and asset testing. Retrieved from https://www.health.govt.nz/our-work/life-stages/health-older-people/long-term-residential-care/income-and-asset-testing

Müller-Nordhorn, J., Nolte, C. H., Rossnagel, K., Jungehülsing, G. J., Reich, A., Roll, S., … Willich, S. N. (2005). The use of the 12-item short-form health status instrument in a longitudinal study of patients with stroke and transient ischaemic attack. *Neuroepidemiology*, *24*(4), 196–202. https://doi.org/10.1159/000084712

New, P. W., & Buchbinder, R. (2006). Critical Appraisal and Review of the Rankin Scale

and Its Derivatives. *Neuroepidemiology*, *26*(1), 4–15. https://doi.org/10.1159/000089536

Niemiec, C. P., Ryan, R. M., & Deci, E. L. (2009). The path taken: Consequences of attaining intrinsic and extrinsic aspirations in post-college life. *Journal of Research in Personality*, *43*(3), 291–306. https://doi.org/10.1016/J.JRP.2008.09.001

Nogueira, R. G., Jadhav, A. P., Haussen, D. C., Bonafe, A., Budzik, R. F., Bhuva, P., … Jovin, T. G. (2018). Thrombectomy 6 to 24 Hours after Stroke with a Mismatch between Deficit and Infarct. *New England Journal of Medicine*, *378*(1), 11–21. https://doi.org/10.1056/NEJMoa1706442

Outpatient Service Trialists. (2003). Therapy-based rehabilitation services for stroke patients at home. *Cochrane Database of Systematic Reviews (Online)*, (1), CD002925. https://doi.org/10.1002/14651858.CD002925

Ozer, M. N., & Kroll, T. (2002). Patient-Centered Rehabilitation: Problems and Opportunities. *Critical Reviews in Physical and Rehabilitation Medicine*, *14*(3–4), 18. https://doi.org/10.1615/CritRevPhysRehabilMed.v14.i34.30

Pandian, J. D., Felix, C., Kaur, P., Sharma, D., Julia, L., Toor, G., … Lindley, R. (2015). FAmily-Led RehabiliTaTion aftEr Stroke in INDia: The ATTEND Pilot Study. *International Journal of Stroke*, *10*(4), 609–614. https://doi.org/10.1111/ijs.12475

Post, M. W. M., Festen, H., van de Port, I. G., & Visser-Meily, J. M. A. (2007). Reproducibility of the Caregiver Strain Index and the Caregiver Reaction Assessment in partners of stroke patients living in the Dutch community. *Clinical Rehabilitation*, *21*(11), 1050–1055. https://doi.org/10.1177/0269215507079140

Quinn, T. J., Dawson, J., Walters, M. R., & Lees, K. R. (2009). Reliability of the Modified Rankin Scale: A Systematic Review. *Stroke*, *40*(10), 3393–3395. https://doi.org/10.1161/STROKEAHA.109.557256

Randall, K. E., & McEwen, I. R. (2000). Writing patient-centered functional goals. *Physical Therapy*, *80*(12), 1197–1203. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/11087306

Rankin, J. (1957). Cerebral Vascular Accidents in Patients over the Age of 60: II.

Prognosis. *Scottish Medical Journal*, *2*(5), 200–215.

https://doi.org/10.1177/003693305700200504

Redfors, P., Isaksén, D., Lappas, G., Blomstrand, C., Rosengren, A., Jood, K., & Jern, C.

(2016). Living alone predicts mortality in patients with ischemic stroke before 70

years of age: a long-term prospective follow-up study. *BMC Neurology*, *16*(1), 80.

https://doi.org/10.1186/s12883-016-0599-y

Riley, J., Evans, H., Kyle-Foulds, E., Retter, A., Allen, D., Fernando, K., & Hunt, A. (2017).

Research clinician reports TaCAS.

Robinson, B. C. (1983). Validation of a Caregiver Strain Index. *Journal of Gerontology*,

38(3), 344–348. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/6841931

Rodrigues, F. B., Neves, J. B., Caldeira, D., Ferro, J. M., Ferreira, J. J., & Costa, J. (2016).

Endovascular treatment versus medical care alone for ischaemic stroke: systematic

review and meta-analysis. *BMJ (Clinical Research Ed.)*, *353*, i1754.

https://doi.org/10.1136/bmj.i1754

Rosenstock, I. M. (1974). Historical Origins of the Health Belief Model. *Health Education

Mographs*, *2*(4), 328–335.

Rosewilliam, S., Roskell, C. A., & Pandyan, A. (2011). A systematic review and synthesis

of the quantitative and qualitative evidence behind patient-centred goal setting in

stroke rehabilitation. *Clinical Rehabilitation*, *25*(6), 501–514.

https://doi.org/10.1177/0269215510394467

Ryan, R. M., & Deci, E. L. (1985). *Self-Determination Theory and the Facilitation of Intrinsic

Motivation, Social Development, and Well-Being Self-Determination Theory*. Ryan.

Retrieved from

https://selfdeterminationtheory.org/SDT/documents/2000_RyanDeci_SDT.pdf

Sandercock, P. A., Counsell, C., Tseng, M.-C., Cecconi, E., Gubitz, G. J., & Tseng, M.-C.

(2014). Oral antiplatelet therapy for acute ischaemic stroke. *Cochrane Database of

Systematic Reviews*, (3). Retrieved from

http://doi.wiley.com/10.1002/14651858.CD000029.pub2

Saver, J. L., Goyal, M., Bonafe, A., Diener, H.-C., Levy, E. I., Pereira, V. M., … Jahan, R. (2015). Stent-Retriever Thrombectomy after Intravenous t-PA vs. t-PA Alone in Stroke. *New England Journal of Medicine*, *372*(24), 2285–2295. https://doi.org/10.1056/NEJMoa1415061

Schuling, J., de Haan, R., Limburg, M., & Groenier, K. H. (1993). The Frenchay Activities Index. Assessment of functional status in stroke patients. *Stroke*, *24*(8), 1173–1177. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/8342192

Scobbie, L., Wyke, S., & Dixon, D. (2009). Identifying and applying psychological theory to setting and achieving rehabilitation goals. *Clinical Rehabilitation*, *23*(4), 321–333. https://doi.org/10.1177/0269215509102981

Statistics New Zealand. (2014). *2013 Census QuickStats about culture and identity*. Wellington, New Zealand. Retrieved from www.stats.govt.nz

Statistics New Zealand. (2017). National ethnic population projections: 2013(base)–2038 (update) | Stats NZ. Retrieved October 26, 2018, from https://www.stats.govt.nz/information-releases/national-ethnic-population-projections-2013base2038-update

Stephens, C., Alpass, F., Baars, M., Towers, A., & Stevenson, B. (2010). *SF-36v2 norms for New Zealanders aged 55-69 years. The New Zealand medical journal* (Vol. 17). Retrieved from https://www.nzma.org.nz/__data/assets/pdf_file/0008/37538/stephens.pdf

Stewart, A., & Ware, J. (1992). *Measuring Functioning and Well-Being: The Medical Outcomes Study Approach*. Duke University Press. https://doi.org/10.7249/CB361

Stroke Foundation. (2017). *Clinical Guidelines for Stroke Management 2017*. Melbourne, Australia.

Stroke Foundation of New Zealand and New Zealand Guidelines Group. (2010). *Clinical Guidelines for Stroke Management 2010*. Wellington.

Stroke Unit Trialists' Collaboration. (1997). Collaborative systematic review of the randomised trials of organised inpatient (stroke unit) care after stroke. Stroke Unit Trialists' Collaboration. *BMJ (Clinical Research Ed.)*, *314*(7088), 1151–1159.

https://doi.org/10.1136/BMJ.314.7088.1151

Stroke Unit Trialists' Collaboration. (2013). Organised inpatient (stroke unit) care for
stroke. *Cochrane Database Sys Rev*, *4*(9), CD000197.
https://doi.org/10.1002/14651858.CD000197.pub3.www.cochranelibrary.com

Synhaeve, N. E., Arntz, R. M., Maaijwee, N. A. M., Rutten-Jacobs, L. C. A.,
Schoonderwaldt, H. C., Dorresteijn, L. D. A., … de Leeuw, F.-E. (2014). Poor Long-
Term Functional Outcome After Stroke Among Adults Aged 18 to 50 Years. *Stroke*,
45(4), 1157–1160. https://doi.org/10.1161/STROKEAHA.113.004411

Taft, C., Karlsson, J., & Sullivan, M. (2001). Do SF-36 summary component scores
accurately summarize subscale scores? *Quality of Life Research : An International
Journal of Quality of Life Aspects of Treatment, Care and Rehabilitation*, *10*(5), 395–404.
Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/11763202

Tan, X., Patel, I., & Chang, J. (2014). Review of the four item Morisky Medication
Adherence Scale (MMAS-4) and eight item Morisky Medication Adherence Scale
(MMAS-8). *Innovations in Pharmacy*, *5*(3). https://doi.org/10.24926/iip.v5i3.347

Tooth, L. R., McKenna, K. T., & Smith, M. (2003). Further evidence for the agreement
between patients with stroke and their proxies on the Frenchay Activities Index.
Clinical Rehabilitation, *17*(6), 656–665. https://doi.org/10.1191/0269215503cr661oa

Tung, C. E., Win, S. S., & Lansberg, M. G. (2011). Cost-Effectiveness of Tissue-Type
Plasminogen Activator in the 3- to 4.5-Hour Time Window for Acute Ischemic
Stroke. *Stroke*, *42*(8), 2257–2262. https://doi.org/10.1161/STROKEAHA.111.615682

van Exel, N. J. A., op Reimer, W. J. S., Brouwer, W. B., van den Berg, B., Koopmanschap,
M. A., & van den Bos, G. A. (2004). Instruments for assessing the burden of informal
caregiving for stroke patients in clinical practice: a comparison of CSI, CRA, SCQ
and self-rated burden. *Clinical Rehabilitation*, *18*(2), 203–214.
https://doi.org/10.1191/0269215504cr723oa

Wade, D. (1992). *Measurement in Neurological Rehabilitation*. Oxford University Press.

Wade, D. (2009). Goal setting in rehabilitation: an overview of what, why and how.

Clinical Rehabilitation, *23*, 291–295. https://doi.org/10.1177/0269215509103551

Wade, D. (2015a). Rehabilitation - A new approach. Overview and Part One: The problems. *Clinical Rehabilitation*. https://doi.org/10.1177/0269215515601174

Wade, D. (2015b). Rehabilitation - A new approach. Part two: The underlying theories. *Clinical Rehabilitation*. https://doi.org/10.1177/0269215515601175

Wade, D. T., & Collin, C. (1988). The Barthel ADL Index: A standard measure of physical disability? *International Disability Studies*, *10*(2), 64–67. https://doi.org/10.3109/09638288809164105

Wade, D T, Legh-Smith, J., & Langton Hewer, R. (1985). Social activities after stroke: measurement and natural history using the Frenchay Activities Index. *International Rehabilitation Medicine*, *7*(4), 176–181. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/4093249

Wade, Derick T. (1998). Evidence relating to goal planning in rehabilitation. *Clinical Rehabilitation*, *12*(4), 273–275. https://doi.org/10.1191/026921598678166365

Wade, Derick T. (2001). Research into the black box of rehabilitation: the risks of a Type III error. *Clinical Rehabilitation*, *15*(1), 1–4. https://doi.org/10.1191/026921501675961253

Wardlaw, J. M., Murray, V., Berge, E., & del Zoppo, G. J. (2014). Thrombolysis for acute ischaemic stroke. *The Cochrane Database of Systematic Reviews*, *7*(7), CD000213. https://doi.org/10.1002/14651858.CD000213.pub3

Ware, J E, & Sherbourne, C. D. (1992). The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. *Medical Care*, *30*(6), 473–483. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/1593914

Ware, John E, Kosinski, M., & Keller, S. D. (1996). A 12-Item Short-Form Health Survey: Construction of Scales and Preliminary Tests of Reliability and Validity. *Medical Care*, *34*(3), 220–233. Retrieved from https://www-jstor-org.helicon.vuw.ac.nz/stable/pdf/3766749.pdf

WHO. (2001a). *International Classification of Functioning, Disability and Health: ICF*. World

Health Organization. https://doi.org/10.1097/01.pep.0000245823.21888.71

WHO. (2001b). The ICF: An Overview. *World Health Organization.*

https://doi.org/htpp/www.who.int.classifications

Williams, L. S., Weinberger, M., Harris, L. E., Clark, D. O., & Biller, J. (1999).

Development of a stroke-specific quality of life scale. *Stroke.*

https://doi.org/10.1161/01.STR.30.7.1362

Wilson, B. A. (2008). Neuropsychological Rehabilitation. *Annual Review of Clinical*

Psychology, *4*(1), 141–162. https://doi.org/10.1146/annurev.clinpsy.4.022007.141212

Wood-Dauphinee, S. L., Williams, J. I., & Shapiro, S. H. (2017). Examining Outcome

Measures in a Clinical Study of Stroke. *Stroke*, *21*, 731–739. Retrieved from

http://stroke.ahajournals.org/

World Health Organisation. (2001). *Towards a Common Language for Functioning, Disability*

and Health: ICF. Geneva. Retrieved from

http://www.who.int/classifications/icf/icfbeginnersguide.pdf?ua=1

8 Appendices

Planned publications

HDEC Ethics Approval

Take Charge Intervention booklet

Participant Information Sheet and Consent

V1, V2, 6m, 12m assessment forms

Published protocol

Table 55. Planned publications

Publication	Author list
Taking Charge after stroke: a randomised controlled trial of a person-centred intervention of self-directed rehabilitation	Vivian Fu, Mark Weatherall, Kathryn McPherson, William Taylor, Anna McRae, Tom Thompson, John Gommans, Matire Harwood, Anna Ranta, Carl Hanger, Harry McNaughton
Meta-analysis of TaCAS and MaPSS results	Mark Weatherall, Vivian Fu, Harry McNaughton
Cost-effectiveness analysis of TaCAS study	Braden Te Ao, Vivian Fu, Mark Weatherall, Harry McNaughton
Qualitative study of TaCAS participants	Kathryn Fernando, Vivian Fu, Harry McNaughton
Analysis of AMP-C as a measurement tool	Vivian Fu, Harry McNaughton
How does the Take Charge session work? A broad review of medical and non-medical literature	Harry McNaughton and others
Follow-up study (mean 3 year follow-up of TaCAS participants)	Potentially a Masters student at MRINZ?

01 September 2015

Dr Harry McNaughton
Neurology Department, CMU
Wellington Hospital
Riddiford St Private Bag 7902
Wellington 6021 Dear

DrMcNaughton

Re:	**Ethics ref:**	**15/CEN/115**
	Study title:	Self-directed rehabilitation RCT after stroke: a practical, low cost programme. The Taking Charge after Stroke (TaCAS) Study

I am pleased to advise that this application has been _approved_ by the Central Health and Disability Ethics Committee. This decision was made through the HDEC-Full Review pathway.

Summary of ethical issues

The main ethical issues considered by the Committee were as follows.

- Dr McNaughton introduced the study. It is a randomised controlled trial of a novel communication intervention for people after they have experienced a stroke. The intervention has been tested before in Maori and Pacific People populations and has been shown to be effective. Therefore, Maori and Pacific Peoples are excluded from the current study. This study is for non-Maori who survive a stroke and who aren't discharged from hospital. Dr McNaughton explained that 15-20 percent of stroke sufferers die in hospital and 15 percent are discharged.

- The Take Charge intervention acknowledges that it is common after stroke to be overwhelmed by such a life changing event. The intervention encourages people to become who they are and take charge of their journey after experiencing a stroke. A focus is placed on who the person is rather than on physical goal setting, such as walking 10 metres in a certain timeframe. Dr McNaughton advised that this type of goal setting has been found not to be effective in transforming people's lives after stroke. The intervention is cheap, and has been found to be very practical and generalizable.

- The research team will recruit only participants who can give informed consent. The committee noted that there may be people who following

a stroke, can understand verbal information but who might struggle to read and asked whether there is an alternative way of getting information to them. Dr McNaughton noted that aphasia following stroke is always a challenge and that he has set the bar that a person will need to understand the information that is in the document and with family/caregiver help can express that they understand. No one will consent on behalf of participants in this study.

- Dr McNaughton explained that in the hospital setting clinicians will be asked to consider whether a person has the ability to understand the information and if not or if the clinician determines that it would be very close they won't refer a patient. Once a patient is referred then the research team will organise a visit and further assess whether a participant will be able to enter the study. The committee noted that it is important that people who are reading impaired but can understand verbal information are included as the benefit could be great.

The committee requested the following changes to the participant information sheet and consent forms:

- Page 3, 'Could this research be stopped unexpectedly?': please remove this paragraph as it is not relevant for this type of study and could be confusing for participants.
- Page 3: the committee noted the information given that a participant's GP will be told about their participation in the study as they may need to contact GPs if new medical problems develop after discharge from hospital or if the research team is unable to contact the participant for final assessments. The committee requested that more specific information is given here about what might happen. For example, high blood pressure and heart rate are critical in this respect.
- Page 4 under the heading 'Will the information collected be confidential?': please replace the words "NZ Multi Regional ethics committee" with the Central Health and Disability Ethics Committee.
- Pages 6 and 7: please review the statements and only include yes/no statements for those that are truly optional.
- Page 6: please remove the interpreter box as there will be no Maori or Pacific Peoples in this study.
- Page 6: please remove the statement "I know who to contact if I have any side effects from the study".
- Page 7, last bullet point: please remove the words "I understand".

Conditions of HDEC approval

HDEC approval for this study is subject to the following conditions being met prior to the commencement of the study in New Zealand. It is your responsibility, and that of the study's sponsor, to ensure that these conditions are met. No further review by the Central Health and Disability Ethics Committee is required.

Standard conditions:

1. Before the study commences at *any* locality in New Zealand, all relevant regulatory approvals must be obtained.

2. Before the study commences at *any* locality in New Zealand, it must be registered in a WHO-approved clinical trials registry (such as the Australia New Zealand Clinical Trials Registry, www.anzctr.org.au).

3. Before the study commences at *a given* locality in New Zealand, it must be authorised by that locality in Online Forms. Locality authorisation confirms that the locality is suitable for the safe and effective conduct of the study, and that local research governance issues have been addressed.

After HDEC review

Please refer to the *Standard Operating Procedures for Health and Disability Ethics Committees* (available on www.ethics.health.govt.nz) for HDEC requirements relating to amendments and other post-approval processes.**our next progress report is due by 27 August 2016.**

Participant access to ACC

The Central Health and Disability Ethics Committee is satisfied that your study is not a clinical trial that is to be conducted principally for the benefit of the manufacturer or distributor of the medicine or item being trialled. Participants injured as a result of treatment received as part of your study may therefore be eligible for publicly-funded compensation through the Accident Compensation Corporation (ACC).

Please don't hesitate to contact the HDEC secretariat for further information. We wish you all the best for your study.

Yours sincerely,
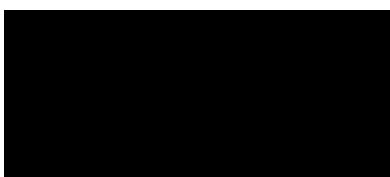
Mrs
Helen
Walker
Chairpe
rson
Central Health and Disability Ethics Committee

Encl: appendix A: documents submitted
        appendix B: statement of compliance and list of members

**Appendix A
Documents
submitted**

Document	Version	Date
CV for CI: CV Dr Harry McNaughton	1	02 August 2015
CVs for other Investigators: CV Dr John Gommans	1	02 August 2015
CVs for other Investigators: CV Dr Geoff Green	1	02 August 2015
CVs for other Investigators: CV Dr Matire Harwood	1	02 August 2015
CVs for other Investigators: CV Prof Mark Weatherall	1	02 August 2015
CVs for other Investigators: CV Assoc Prof William Taylor	1	02 August 2015
CVs for other Investigators: CV Dr Carl Hanger	1	02 August 2015
CVs for other Investigators: CV Dr Anna Ranta	1	02 August 2015
Survey/questionnaire: Six month Outcome form	Six month v2	02 August 2015
Survey/questionnaire: 12 month outcome form	12 month v2	02 August 2015
Evidence of scientific review: HRC letter confirming successful application and funding	1	27 May 2015
Take Charge Session sheet	v2	02 August 2015
Survey/questionnaire: Baseline assessment form	Baseline v2	02 August 2015
PIS/CF: Patient Info and consent form	v4	02 August 2015
Protocol: Protocol	v5	01 August 2015
Covering Letter: Cover letter	v1	10 August 2015

Appendix B
Statement of compliance and list of members

Statement of compliance

The Central Health and Disability Ethics Committee:

— is constituted in accordance with its Terms of Reference
— operates in accordance with the *Standard Operating Procedures for Health and Disability Ethics Committees*, and with the principles of international good clinical practice (GCP)
— is approved by the Health Research Council of New Zealand's Ethics Committee for the purposes of section 25(1)(c) of the Health Research Council Act 1990
— is registered (number 00008712) with the US Department of Health and Human Services' Office for Human Research Protection (OHRP).

List of members

Name	Category	Appointed	Term Expires	Present on 25/08/2015?	Declaration of interest?
Mrs Helen Walker	Lay (consumer/community perspectives)	01/07/2012	01/07/2015	Yes	No
Dr Angela Ballantyne	Lay (ethical/moral reasoning)	01/07/2015	01/07/2018	No	No
Dr Melissa Cragg	Non-lay (observational studies)	01/07/2015	01/07/2018	No	No
Dr Peter Gallagher	Non-lay (health/disability service provision)	01/07/2015	01/07/2018	Yes	No
Mrs Sandy Gill	Lay (consumer/community perspectives)	01/07/2015	01/07/2018	Yes	No
Dr Patries Herst	Non-lay (intervention studies)	01/07/2012	01/07/2015	Yes	No
Dr Dean Quinn	Non-lay (intervention studies)	01/07/2012	01/07/2015	Yes	No
Dr Cordelia Thomas	Lay (ethical/moral reasoning)	19/05/2014	19/05/2017	Yes	No

Unless members resign, vacate or are removed from their office, every member of HDEC shall continue in office until their successor comes into office (HDEC Terms of Reference)

http://www.ethics.health.govt.nz

Taking Charge after Stroke:
The TaCAS study

Confidential:

Please only use this booklet with people randomised to the Take Charge intervention as part of the TaCAS trial

Taking Charge

For example: weak, hard to talk, hard to walk, feel funny, tired, can't concentrate, lonely, sad, can't work, need help

For example: Mother, daughter, wife, choir member, helper, walker, gardener, grandma, teacher, friend, reader, joker, volunteer, strong, happy, energetic, warm, kind, gentle and lots more!

My Stroke

Me

A stroke person

Who I really am

My stroke

A person who happens to have had a stroke

Taking Charge after Stroke

Overall hopes, aims, aspirations for next 12 months

1.
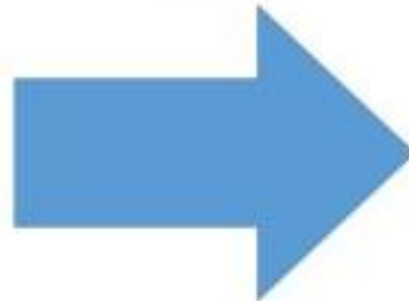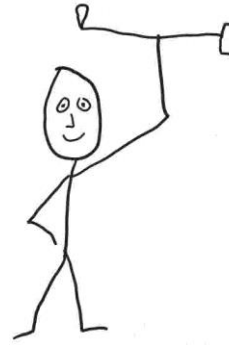
2.

3.

4.
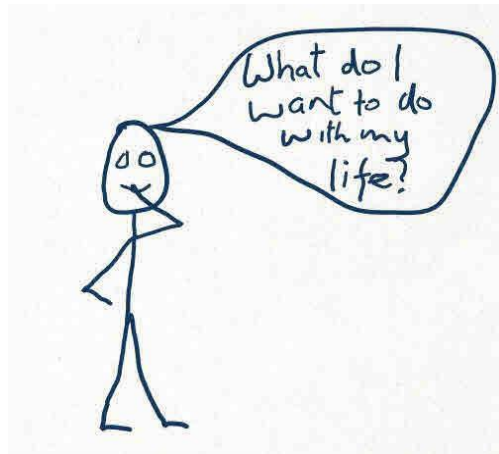
Main fears

1.

2.

3.
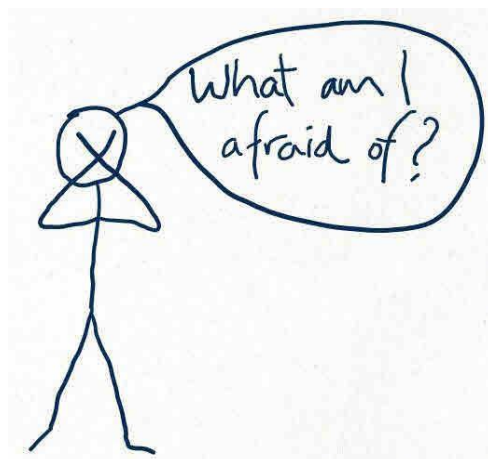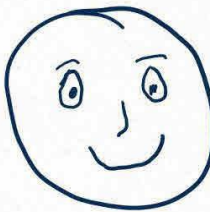
What would my 'Best Day' look like?

Draw a picture of your best day here.   Friends and family may also want to draw something.

Physical things like getting around, washing and dressing, doing the housework
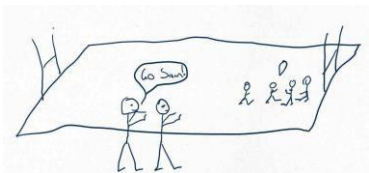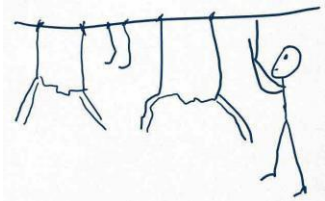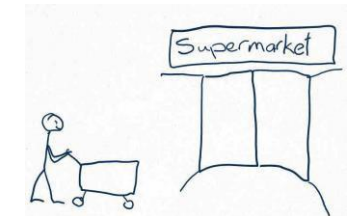
Date	Goals (in own words)	Specific objectives and time frame	How to achieve these
eg	To walk to the shop on my own	1. Walk unaided – 1 month 2. Walk unaided 200m – 3 months 3. Walk to shop – 6 months	1. Walking practice with support person present five times per week 2. Physio advice about stick and walking frame
		1. 2. 3.	1. 2. 3.
		1. 2. 3.	1. 2. 3.
		1. 2. 3.	1. 2. 3.

Communication including speech, understanding, reading, writing, using a computer
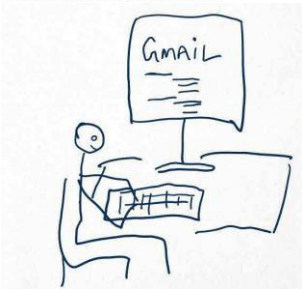
Date	Goals (in own words)	Specific objectives and time frame	How to achieve these
eg	To be able to answer the telephone	1. To be confident talking to someone I know - 2 months 2. To be confident talking on the telephone to someone I know - 4 months	1. Lots of practice with people I know 2. Use answerphone until confident answering phone myself.
		1. 2. 3.	1. 2. 3.
		1. 2. 3.	1. 2. 3.
		1. 2. 3.	1. 2. 3.

Emotional issues like feeling anxious, worried, stressed, depressed, helpless
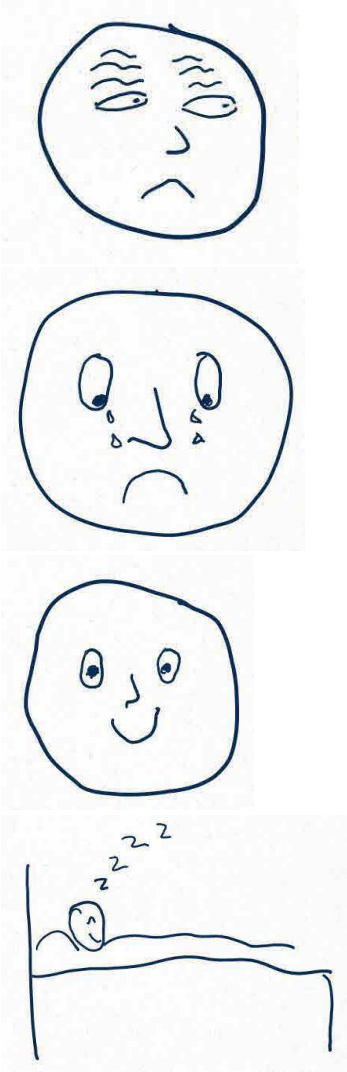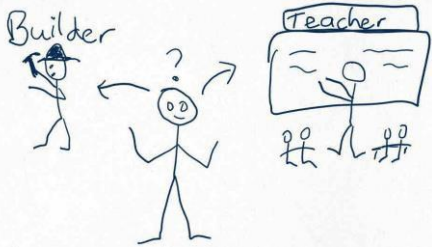
Date	Goals (in own words)	Specific objectives and time frame	How to achieve these
eg	To feel in control/charge	1. Look at my main hopes for the next 12 months every week 2. Sleep 6 hours/night + nap 1 hour .	1. Put my 'main hopes' sheet on the fridge door where I can see it 2. Join a support group?
		1. 2. 3.	1. 2. 3.
		1. 2. 3.	1. 2. 3.
		1. 2. 3.	1. 2. 3.

Information needs
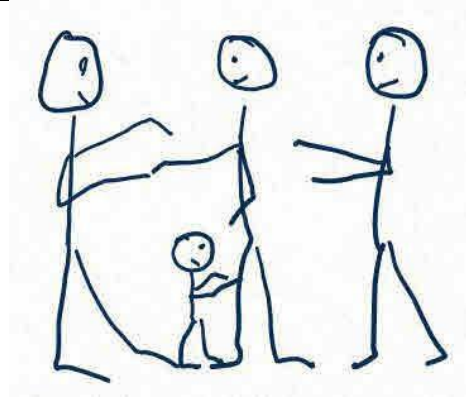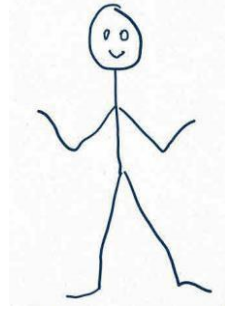
	Date	Goals (in own words)	Specific objectives and time frame	How to achieve these
	Eg.	*Understand what happened and why*	*1. Understand what stroke is* *2. Understand why stroke occurred* *3. Understand rehabilitation*	*1. Talk to other people, including Stroke Foundation, doctor, internet (www.stroke.org.nz)*
			1. 2. 3.	1. 2. 3.
			1. 2. 3.	1. 2. 3.
			1. 2. 3.	1. 2. 3.

Financial issues like paying the bills, returning to work, using a budget, knowing about available supports

	Date	Goals (in own words)	Specific objectives and time frame	How to achieve these
	eg	To reduce travel costs	1. Mobility car sticker 2. Taxi chits and other supports 3. Informed about WINZ support	1. GP to provide 2. Stroke foundation, local providers 3. WINZ information
			1. 2. 3.	1. 2. 3.
			1. 2. 3.	1. 2. 3.
			1. 2. 3.	1. 2. 3.

My support network – where I go for help, support, having a good time

	Date	Goals (in own words)	Specific objectives and time frame	How to achieve these
	eg	*To get more of my support team involved*	*1. Support team understand my main hopes for the future* *2. Enough help for me and my carers*	*1. Information/SF/support group* *2. Meet with support needs assessor (GP can arrange)*
			1. 2. 3.	1. 2. 3.
Stroke Foundation of NZ -www.stroke.org.nz , Community stroke advisors , Stroke clubs 0800 STROKE			1. 2. 3.	1. 2. 3.
			1. 2. 3.	1. 2. 3.

Preventing strokes and heart attacks in the future

Blood pressure

Smoking

Diet

Exercise

Atrial fibrillation (AF)

Diabetes

Date	Goals (in own words)	Specific objectives and time frame	How to achieve these
Eg.	*To reduce my risk of stroke (my problems are high blood pressure, diabetes and cigarettes!)*	*1. BP < 135/80* *2. HbA1C < 50* *3. Quit smoking*	*1. Reduce salt, take medicines, measure myself at home* *2. Nutrition and exercise* *3. Enrol quit programme*
		1. 2. 3.	1. 2. 3.
		1. 2. 3.	1. 2. 3.
		1. 2. 3.	1. 2. 3.

BP Target
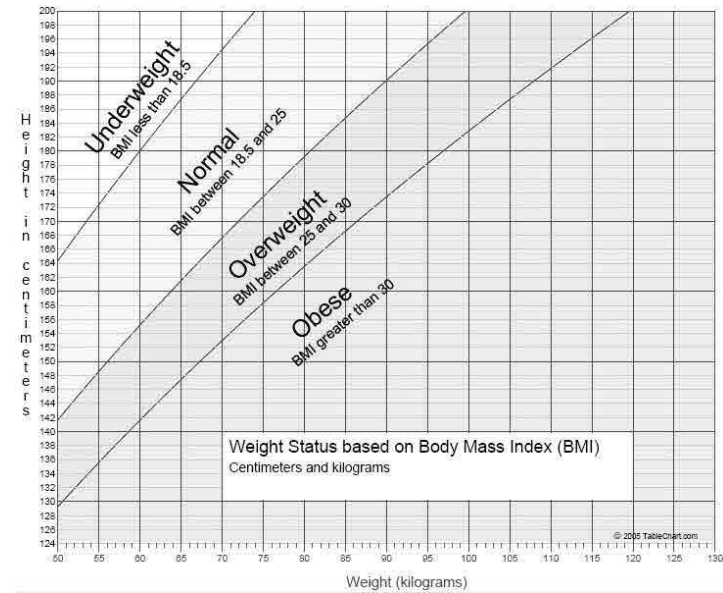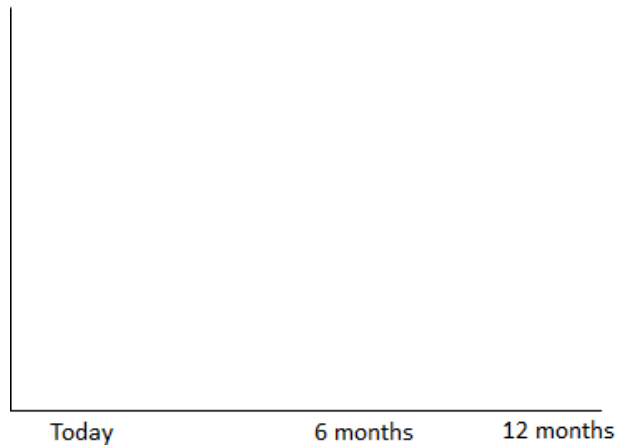
135

80

Today   6 months   12 months

Exercise Target

minutes per week

150

Today   6 months   12 months

Your Target for _____

Today   6 months   12 months

Height in centimeters

Underweight
BMI less than 18.5

Normal
BMI between 18.5 and 25

Overweight
BMI between 25 and 30

Obese
BMI greater than 30

Weight Status based on Body Mass Index (BMI)
Centimeters and kilograms

© 2005 TableChart.com

Weight (kilograms)

Taking Charge

For example: weak, hard to talk, hard to walk, feel funny, tired, can't concentrate, lonely, sad, can't work, need help

For example: Mother, daughter, wife, choir member, helper, walker, gardener, grandma, teacher, friend, reader, joker, volunteer, strong, happy, energetic, warm, kind, gentle and lots more!

My Stroke

Me

A stroke person

Who I really am

My stroke

A person who happens to have had a stroke

Taking Charge after Stroke

Overall hopes, aims, aspirations for next 12 months

1.

2.

3.

4.

Main fears

1.

2.

3.

Taking Charge after Stroke: The TaCAS study

Dear _____

I wish to invite you to consider taking part in the Taking Charge after Stroke study (TaCAS for short). This is a study looking at ways to improve life after stroke. With this letter you will have been given a 'Participant Information and Consent Form' about the study which I encourage you and your family to read. If you are interested in taking part, one of our research staff will phone you once you are home from hospital to organise to meet you at home.

If you agree to participate you will have one or two visits at home by a research clinician (either a nurse or other health professional). They will ask you some questions about how you are doing and check your blood pressure and pulse. Then you will receive either some excellent written material about stroke and stroke prevention from the Stroke Foundation, or one or two Take Charge sessions. The Take Charge session is a type of interview aiming to help you get the most out of your life. It doesn't involve any new medicines or injections. This is all in addition to your usual rehabilitation following your stroke. We will check how you are getting on about 6 months after your stroke and ask you some important questions. You will have the option of choosing to complete these questions with us on the telephone, or in your own time via a questionnaire posted to you or completed on the Internet. We will visit you again after 12 months to check on your progress.

Feel free to ask any of our team questions about the study. Thanks very much for reading this letter.

Best wishes

Dr Harry McNaughton
Principal investigator, Taking Charge after Stroke study
Contact: ▮▮▮▮▮▮▮▮

Local contact:

What happens, when and where:

What	When	Where
What	**When**	**Where**
Stroke happened	Day 0	Hospital
⬇		
Read this letter and information sheet	Days-few weeks	Hospital
⬇		

Not OK ← OK with idea of study

⬇		
Usual care only	Phone call from research person	1-2 weeks after getting home from hospital — Home

⬇

1st visit at home — Between 3-15 weeks after your stroke — Home

1/3rd have 2nd visit   ⬇   2/3rds have one visit only — 6 weeks after 1st visit — Home

We contact you and check on your progress — 6 months after your stroke — Home (phone call)

Last visit check on progress — 12 months after your stroke — Home

⬇

Results of overall study available — End of 2018

	PARTICIPANT INFORMATION	
	and CONSENT FORM	
	Taking Charge after Stroke study	

Study ID [ ] [ ] [ ] [ ]

Introduction

You are invited to take part in this research study, called the Taking Charge after Stroke (TaCAS) study, which aims to find out whether one or two 'Take Charge sessions', designed to help people 'take charge' of their lives following stroke, improve their quality of life and need for help from other people. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with the doctor or nurse if you wish. You may also have a friend, family or other support person to help you understand the risks and/or benefits of this study and any other explanation you may require before you decide whether or not to take part.

What is the background to and purpose of the study?

You have recently had a stroke and have not completely recovered; for example you may still have impaired function of your limbs, speech, or eyesight. Standard rehabilitation therapy by a team of doctors, nurses and therapists has been shown to help people recover from their stroke but despite this, recovery may not be as good as hoped for.

The **Taking Charge after stroke** study is being carried out to see whether people with stroke who, in addition to their usual care, have one or two 'take charge sessions' with a trained health professional recover better than those who, in addition to their usual care, are given written information about stroke recovery and prevention. People, who are admitted to hospital with a stroke and then discharged to their own home or that of a relative/friend (i.e. not a rest home or private hospital) will be invited to participate in this study. This study will involve about 400 people with a stroke from around New Zealand.

The study is being run by a group of stroke doctors from around New Zealand. It is independent of any pharmaceutical company and is being funded by a research grant from the New Zealand Health Research Council.

Do I have to take part?

Your participation is entirely voluntary (your choice). You do not have to take part in this study, and if you choose not to take part you will receive the usual treatment for people with stroke. If you do agree to take part, you are free to withdraw completely from the study at any time, without having to give a reason and this will in no way affect your continuing health care.

Who is eligible to participate?

To be eligible to participate in this study you must be aged 16 years or older and meet **all of the following Inclusion Criteria:**

- Have had a new diagnosis of stroke.

- Have a persisting measurable disability from the stroke (such as loss of strength, sensation, vision, speech, walking ability).

You will **NOT** be eligible to participate if you have **any of the following Exclusion Criteria**:

- Māori or Pacific ethnicity - as the previous Take Charge study has already shown that the Take Charge session definitely improved outcome in Māori and Pacific people after stroke. In this study we are testing the Take Charge session in people who are NOT Māori and Pacific

- Not available for follow up for the next 365 days e.g. no fixed home address

- Have any other life threatening illness such as advanced cancer.

What will happen if I decide to participate?

If you agree to participate, you will be randomly allocated (like flipping a coin) to one of three groups:

1. One Take Charge session

2. Two Take Charge sessions with the second one 6 weeks after the first

3. Written educational material about stroke recovery and prevention

Contact details for all participants, and a support person they choose, will be recorded to enable the study team to follow you later to find out how things are going. A member of the study team will complete a few short health questionnaires with you to check your functional abilities [what you can and cannot do] and risk factors for future stroke, including measuring your heart rate, blood pressure, weight and height. We may also need to check your hospital records for any hospital admissions or attendances during the study period.

If you are in one of the Take Charge groups a trained health professional will work with you, and any family members or friends you would like to be present, to 'take charge' of your life after stroke. The 'Take Charge session' takes about 50 minutes and will look at the things that you want to achieve in your life and the steps needed to do that.

You will receive the same basic care as given to all patients with stroke and your participation will not restrict the options of your doctor to manage your care and treatment in the best way.

Treatment Period and Follow Up

If you agree to participation in this study you will have two further assessments at 6 and 12 months after your stroke. These will be done by a different person to the person you met at the start and they won't know which group you are in. We ask that you do not tell them. The 6 months assessment will be done by written or Internet-based questionnaire, with the option of asking you the questions by telephone if you prefer. A short telephone call may be used to follow-up on any

missing responses. The assessment at 12 months will be face to face – either at your home or somewhere else that suits you.

At these follow-up assessments the study assessor will ask you:

- about your functional ability (what you can and cannot do every day around the house), and how you are feeling

- any new medication you are taking

- any use of health care such as rehabilitation therapy sessions

The 6 month assessment will take about 15 minutes and the 12 month visit will take 30-45 minutes.

We will inform your GP of your participation in the study. We will also let them know if there are any potentially important problems with your blood pressure or pulse when we measure these. We may need to contact them if we are unable to contact you for the final assessments.

What are the possible side effects and risks of taking part?

The Take Charge session is safe and no side effects were seen in the previous study that was done. There are no new medications or physical treatments as part of the Take Charge session.

What are the possible benefits of taking part?

The study treatments may improve your long-term recovery. However, we cannot promise that you will receive such benefits. All participants will have access to follow-up and care by the study medical team and nursing staff. The results of the trial will contribute to medical knowledge and if positive, will help improve the outcome of future stroke patients.

What if new information becomes available?

You will be told by the research doctor/nurse if any new information about stroke management or the study treatment becomes available which may influence your opinion on whether you would want to continue in the study.

What are the costs of taking part?

Your participation in the study will not cost you anything. The first assessment and the final follow-up visit will be at home or somewhere convenient for you.

The study is funded by the New Zealand Health Research Council and no member of the research team is being directly paid for including you in this study.

What are the compensation provisions for the study?

If you were injured in this study, which is unlikely, you would be eligible for compensation from ACC just as you would be if you were injured in an accident at work or at home. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.

If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won't affect your cover.

If you have questions about ACC, contact your nearest ACC office or the investigator.

Will the information collected be confidential?

If you consent to taking part in the study your local research doctor and/or nurse will record information about you, your medical condition and your progress. This information will be transferred to the research centre monitoring the study and will be used to determine if the Take Charge session has any benefits. All the information about you (both electronic data and information in paper files) will be stored securely (for 10 years after the study finishes) and kept confidential. The research staff who handle your information will also comply with all relevant privacy legislation.

An auditor or study monitor appointed by either the Taking Charge after Stroke Study steering committee, ethics committee or the regulatory authority or their approved representative and approved by the Central Health and Disability Ethics Committee may inspect your medical records for the sole purpose of checking the accuracy of the information recorded for the study.

The results of the study will be published in medical journals and may be sent to Health Authorities. However, any personal details will be kept strictly confidential and no material that could personally identify you will be used in any reports on this study.

How will I find out about the results?

Once the results are available we will provide you with information about our website where you can also find out about the results of the study and will arrange to send a summary of these to you if you wish. Please note that this trial will take about 3 years to complete and then further time for all the information to be analysed so there may be a significant delay before the results are available.

What if I have other concerns?

Please feel free to contact one of the study team if you have any questions about this study or if you develop a problem which you suspect may have resulted from your involvement in this study.

Study co-ordinator: **Dr Harry McNaughton**
Position: **Neurologist**
Address: **Neurology Department, Wellington Hospital**
Phone No: ▮▮▮▮▮▮▮

Local study contact:

If you have any queries or concerns *about your rights as a participant* in this research study, you can contact an independent health and disability advocate. This is a free service provided under the Health and Disability Commissioner Act 1994.

> Telephone (NZ wide): 0800 555 050

> Free Fax (NZ wide): 0800 2787 7678 (0800 2 SUPPORT)

> Email (NZ wide): advocacy@hdc.org.nz

This study has received ethical approval from the Central Health & Disability Ethics Committee (reference 15/CEN/115).

You can contact them at
> Post PO Box 5013 Wellington 6011,
> Phone 0800 4 ETHICS
> email: hdecs@moh.govt.nz

You will be given a copy of this Participant Information Sheet and your signed Consent Form to keep.

CONSENT FORM: to participate in the Taking Charge after Stroke Study

I have read or have had read to me and understand the Participant Information and Consent Form.	YES	
I have had the opportunity to use family support or a friend to help me ask questions and understand the study.	YES	
I understand that taking part in this study is voluntary (my choice), and that I may withdraw from the study at any time, and this will in no way affect my future or continuing health care.	YES	
I understand that my participation in this study is confidential and that no material that could identify me will be used in any reports on this study.	YES	
I understand the compensation provisions for this study.	YES	
I have had time to consider whether to take part in the study.	YES	
I understand that I can choose to have the first follow-up assessment done via telephone call, a written questionnaire posted or emailed to me, or completed on the Internet.	YES	
I know who to contact if I have any questions about the study.	YES	
I agree to an approved auditor appointed by either the Taking Charge after Stroke (TaCAS) Study steering committee, ethics committee or the regulatory authority or their approved representative reviewing my relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study.	YES	
I agree to appropriate members of the study team collecting and processing my information (including my name and contact details and information about my health) and searching electronic medical records for details of my hospital admissions and attendances during the study period. I understand that this information will be stored securely for 10 years and kept confidential.	YES	
I agree to my GP or other current healthcare provider being informed of my participation in this study.	YES	
I wish to receive a copy of the study results. There may be a significant delay before these results are available.	YES	NO

Participant's Consent

I, …………………………………………..………..
(*Participants printed full name*)

hereby consent to take part in this study.

Date: ……………………

Study ID □ □ □ □

Witness/Other signatory Statement

Signed on behalf of participant and with participant's full consent by:

……………………………………..……..…………..……… (Printed full name)

Signature: …………………………………….Date: …………………

Due to: …………………………………………..…..(e.g. Participant's inability to write)

Relationship to participant: ………………………………………..……

Project explained by

(Printed name):…………………………………………………….

Project role:…………………………………………………………

Signature: …………………………….………. Date: …………

Baseline Home Visit Worksheet 1

Participant Initials:

DATE: _____/_____/ _____

(DD / MM / YYYY)

INFORMED CONSENT

(Use Participant Information Sheet: 2 copies to be signed – one to be retained at site and one given to participant)

Informed consent procedures were completed with this participant prior to any study procedures being done.	☐ Yes / ☐ No
Participant consented?	☐ Yes / ☐ No
Originals to file	☐
Second signed copy to subject	☐
Informed consent declined Reason (if given):	☐
Sign:	Date:

CURRENT MEDICATIONS

Fluoxetine *(antidepressant)*	☐ Yes / ☐ No
Anti-hypertensive *(eg: cilazapril, quinapril, enalapril, candesartan, Losartan, felodipine, amlopidine, diltiazem, bendrofluazide, frusemide, carvedilol, metoprolol, atenolol)*	☐ Yes / ☐ No
Anti-coagulant	☐ Yes / ☐ No
(*Select*): ☐ warfarin / ☐ dabigatran	
Anti-platelet	☐ Yes / ☐ No
(*Select*): ☐ clopidogrel / ☐ aspirin	
Cholesterol lowering medication *(a statin, usually atorvastatin or simvastatin, ezetimibe, bezafibrate or gemfibrozil)*	☐ Yes / ☐ No
Initial:	Date:

Taking Charge After Stroke – **TaCAS**   **STUDY ID** ☐☐☐☐

BASELINE ASSESSMENTS

Modified Rankin Score *Tick appropriate number*	0 = No symptoms or signs 1 = Symptoms and/or signs but no disability 2 = Disability but independent in usual daily activities 3 = Requires help for 1 or more daily activities but still mobile 4 = Dependent and needs help for mobility 5 = Bed bound

Barthel Index	*Tick appropriate number for each item*
Feeding	☐ 0 = unable ☐ 1 = needs help eg cutting, spreading ☐ 2 = independent
Bathing	☐ 0 = dependent ☐ 1 = independent
Grooming	☐ 0 = needs help with personal care ☐ 1 = independent face/hair/teeth/shaving (implements provided)
Dressing	☐ 0 = dependent ☐ 1 = needs help but can do about half unaided ☐ 2 = independent (including buttons, zips, laces etc)
Bowels	☐ 0 = incontinent (or needs to be given enemas) ☐ 1 = occasional accident ☐ 2 = continent
Bladder	☐ 0 = incontinent, or catheterised/sheath and unable to manage alone ☐ 1 = occasional accident ☐ 2 = continent
Toilet use	☐ 0 = dependent ☐ 1 = needs some help, but can do something alone ☐ 2 = independent (on and off, dressing, wiping)
Transfers (Bed to chair and back)	☐ 0 = unable, no sitting balance ☐ 1 = major help (1 or 2 people, physical), can sit ☐ 2 = minor help (physical or verbal) ☐ 3 = independent
Mobility (on level surfaces)	☐ 0 = immobile or < 10 m ☐ 1 = wheelchair independent, including corners, > 10 m ☐ 2 = walks with help of 1 person (verbal or physical) >10 m ☐ 3 = independent (but may use aid such as stick) > 10 m
Stairs	☐ 0 = unable ☐ 1 = need help (verbal, physical, carrying aid) ☐ 2 = independent

Taking Charge After Stroke – TaCAS

STUDY ID ☐ ☐ ☐ ☐

Frenchay activities index	*Tick appropriate number for each item (as assessed at the time of the study visit or in the week prior i.e. assessment of current situation)*
1. Preparing meals	☐ 0 = never ☐ 1 = <1x/week ☐ 2 = 1-2x/week ☐ 3 = most days
2. Washing up	☐ 0 = never ☐ 1 = <1x/week ☐ 2 = 1-2x/week ☐ 3 = most days
3. Washing clothes	☐ 0 = never ☐ 1 = 1-2x/3 months ☐ 2 = 3-12x/3 months ☐ 3 = at least weekly
4. Light housework	☐ 0 = never ☐ 1 = 1-2x/3 months ☐ 2 = 3-12x/3 months ☐ 3 = at least weekly
5. Heavy housework	☐ 0 = never ☐ 1 = 1-2x/3 months ☐ 2 = 3-12x/3 months ☐ 3 = at least weekly
6. Local shopping	☐ 0 = never ☐ 1 = 1-2x/3 months ☐ 2 = 3-12x/3 months ☐ 3 = at least weekly
7. Social occasions	☐ 0 = never ☐ 1 = 1-2x/3 months ☐ 2 = 3-12x/3 months ☐ 3 = at least weekly
8. Walking outside > 15 mins	☐ 0 = never ☐ 1 = 1-2x/3 months ☐ 2 = 3-12x/3 months ☐ 3 = at least weekly
9. Actively pursuing hobby	☐ 0 = never ☐ 1 = 1-2x/3 months ☐ 2 = 3-12x/3 months ☐ 3 = at least weekly
10. Driving car/ going on bus	☐ 0 = never ☐ 1 = 1-2x/3 months ☐ 2 = 3-12x/3 months ☐ 3 = at least weekly
11. Travel outings/ car rides	☐ 0 = never ☐ 1 = 1-2x/6 months ☐ 2 = 3-12x/6 months ☐ 3 = at least 2x weekly

12. Gardening	☐ 0 = never ☐ 1 = light ☐ 2 = moderate ☐ 3 = all necessary
13. Household/car maintenance	☐ 0 = never ☐ 1 = light ☐ 2 = moderate ☐ 3 = all necessary
14. Reading books	☐ 0 = none ☐ 1 = 1 in 6 months ☐ 2 = <1 per fortnight ☐ 3 = >1 per fortnight
15. Gainful work	☐ 0 = none ☐ 1 = up to 10 hr/week ☐ 2 = 10-30 hr/week ☐ 3 = >30 hr/week

Circle appropriate comment for each item

Purpose Autonomy Mastery Connectedness (PAM-C)

1. My life has a clear sense of purpose.	Disagree strongly	Disagree	Agree	Agree strongly	N / A
2. I feel in control of my life.	Disagree strongly	Disagree	Agree	Agree strongly	N / A
3. I have the skills to make the most of my life.	Disagree strongly	Disagree	Agree	Agree strongly	N / A
4. I feel connected with the important people in my life.	Disagree strongly	Disagree	Agree	Agree strongly	N / A

Tick appropriate number for each item

PHQ-2

Over the past 2 weeks how often have you been bothered by any of the following Problems?	Not at all	Several days	More than half the days	Nearly every day
1. Little interest or pleasure in doing things	☐ 0	☐ 1	☐ 2	☐ 3
2. Feeling down, depressed or hopeless	☐ 0	☐ 1	☐ 2	☐ 3

Taking Charge After Stroke – **TaCAS**

Short Form 12 v2

This questionnaire asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

For each of the following questions, please mark an ⊠ in the one box that best describes your answer.

1. **In general, would you say your health is:**

Excellent	Very good	Good	Fair	Poor
▼	▼	▼	▼	▼
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

2. **The following questions are about activities you might do during a typical day. Does <u>your health now limit you</u> in these activities? If so, how much?**

	Yes, limited a lot ▼	Yes, limited a little ▼	No, not limited at all ▼
a <u>Moderate activities</u>, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf..........................	☐ 1	☐ 2	☐ 3
b Climbing <u>several</u> flights of stairs..	☐ 1	☐ 2	☐ 3

3. **During the <u>past 4 weeks</u>, how much of the time have you had any of the following problems with your work or other regular daily activities <u>as a result of your physical health</u>?**

	All of the time ▼	Most of the time ▼	Some of the time ▼	A little of the time ▼	None of the time ▼
a <u>Accomplished less</u> than you would like	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b Were limited in the <u>kind</u> of work or other activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

4. **During the <u>past 4 weeks</u>, how much of the time have you had any of the following problems with your work or other regular daily activities <u>as a result of any emotional problems</u> (such as feeling depressed or anxious)?**

	All of the time ▼	Most of the time ▼	Some of the time ▼	A little of the time ▼	None of the time ▼
a <u>Accomplished less</u> than you would like	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b Did work or other activities <u>less carefully than usual</u>	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

5. **During the <u>past 4 weeks</u>, how much did <u>pain</u> interfere with your normal work (including both work outside the home and housework)?**

Not at all ▼	A little bit ▼	Moderately ▼	Quite a bit ▼	Extremely ▼
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

6. **These questions are about how you feel and how things have been with you <u>during the past 4 weeks</u>. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the <u>past 4 weeks</u>…**

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a Have you felt calm and peaceful?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b Did you have a lot of energy?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c Have you felt downhearted and depressed?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

7. **During the <u>past 4 weeks</u>, how much of the time has your <u>physical health or emotional problems</u> interfered with your social activities (like visiting with friends, relatives, etc.)?**

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Below are some statements that people sometimes make when they talk about their health. Please indicate how much you agree or disagree with each statement as it applies to you personally by circling your answer. Your answers should be what is true for you and not just what you think others want you to say.

If the statement does not apply to you, circle N/A.

1.	When all is said and done, I am the person who is responsible for taking care of my health	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
2.	Taking an active role in my own health care is the most important thing that affects my health	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
3.	I am confident I can help prevent or reduce problems associated with my health	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
4.	I know what each of my prescribed medications do	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
5.	I am confident that I can tell whether I need to go to the doctor or whether I can take care of a health problem myself	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
6.	I am confident that I can tell a doctor concerns I have even when he or she does not ask	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
7.	I am confident that I can follow through on medical treatments I may need to do at home	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
8.	I understand my health problems and what causes them	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
9.	I know what treatments are available for my health problems	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
10.	I have been able to maintain (keep up with) lifestyle changes, like eating right or exercising	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
11.	I know how to prevent problems with my health	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
12.	I am confident I can figure out solutions when new problems arise with my health	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
13.	I am confident that I can maintain lifestyle changes, like eating right and exercising, even during times of stress	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A

Taking Charge After Stroke – **TaCAS**

STUDY ID

RISK FACTOR ASSESSMENT

Weight	(kg)	
Height	(m)	
Heart Rate	(bpm)	
Pulse rhythm	☐ regular / ☐ not regular	
Irregular rhythm and not on anti-anticoagulant	☐ Yes‡ / ☐ No	
Atrial fibrillation (AF) previously diagnosed	☐ Yes / ☐ No	
Heart rate >120 bpm?	☐ Yes‡ / ☐ No	
Heart rate <40 bpm?	☐ Yes‡ / ☐ No	
Blood pressure (BP)	/ (mmHg)	Systolic <80 or >180 ☐ Yes‡ / ☐ No
Diabetes	☐ Yes / ☐ No	Treated: ☐ Yes / ☐ No
Current smoker	☐ Yes / ☐ No	
Initial:	Date:	

‡Discuss with participant notification to Primary Investigator

Outcome: _____

REHABILITATION AND SUPPORT (Self-Reported)

Current rehab service involvement	☐ Yes / ☐ No
Hours of face-to-face rehab time in past week	
Current hours/ week home help (paid)	
Current hours/ week personal cares (paid)	
Current support adequate	☐ Yes / ☐ No
Do you have an unpaid carer / main support person?	☐ Yes / ☐ No
If yes, roughly how much per week does it cost your unpaid carer/s to support you (eg lost wages, transport)?	/ week
Initial:	Date:

Taking Charge After Stroke – **TaCAS**

STUDY ID [ ][ ][ ][ ]

WORK (Self-reported)

Paid work before this stroke	☐ Yes / ☐ No
If yes average take home pay per week before this stroke (does not include ACC or other benefit/allowance-based income)	☐ Does not wish to disclose
Paid work since this stroke? (not including sick pay)	☐ Yes / ☐ No
Reduction in hours/pay since this stroke? (%)	/ % reduction ☐ Does not wish to disclose
Initial:	Date:

INCLUSION / EXCLUSION CRITERIA

Inclusion Criteria (any 'no' will exclude)

1. Signed informed consent form	Yes / No
2. Able and willing to comply with study protocol requirements	Yes / No
3. Age ≥ 16 years	Yes / No
4. Non-Māori, non-Pacific ethnicity	Yes / No
5. Incomplete recovery from this stroke *(i.e Modified Rankin Score (mRS) must be >0)*	Yes / No

Exclusion Criteria (any 'yes' will exclude)

1. Unable to provide informed consent	Yes / No
2. Advanced disease making survival unlikely at 12 month follow-up	Yes / No
3. Discharged to institutional community living situation	Yes / No
4. Significant aphasia or cognitive problem thus making consent unreliable (determined at investigator discretion)	Yes / No
5.	

Did the subject meet all eligibility criteria?   ☐ Yes / ☐ No

Comments_____

Initial:	Date:

Taking Charge After Stroke – **TaCAS**   STUDY ID ☐☐☐

RANDOMISATION

Suitable for randomisation: ☐ Yes / ☐ No

Envelope Number: ☐☐☐

Assigned to: ☐ TaCAS 1 / ☐ TaCAS 2 / ☐ Stroke Foundation Information

Initial: **Date:**

INTERVENTION COMPLETED

TaCAS 1   ☐

TaCAS 2 (first intervention)   ☐

Stroke Foundation Information given   ☐

How many support people present: 0 / 1 / 2 / >2

Was one of these people your spouse/partner: ☐ Yes / ☐ No

Who is going to be your main support person through the next 12 months?

_____

Intervention Completed by:

Initial: **Date**

VISIT 2 ARRANGEMENTS FOR TaCAS 2 GROUP ONLY

Date*:____/____/_____   Time:_____:_____   ☐ Entered into study calendar

* six weeks post first TaCAS session +/- 7 days

Taking Charge After Stroke – **TaCAS**

ARRANGEMENTS FOR 6 MONTH FOLLOW-UP (ALL PARTICIPANTS):

Preferred method of follow-up (please circle):

Telephone / Posted questionnaire / Electronic web-based questionnaire

Anticipated date of phone follow-up**:_____/_____/_____

Preferred time for phone call:_____:_____

** must be six months post stroke +/- 14 days

Research Clinician comment

What went well during this session?

_____

_____

What did not go well?

_____

_____

What "stand out" comments were there from the participant?

_____

_____

Visit completed by:

Name:	Sign:	Date:
Name:	Sign:	Date:

Worksheet for TaCAS 2 group (second intervention)

Participant Initials: **DATE:** _____/_____/_____

(Visit 6 weeks after date of baseline visit +/- 7 days)

BASELINE ASSESSMENTS

Modified Rankin Score *Tick appropriate number*	☐ 0 = No symptoms or signs ☐ 1 = Symptoms and/or signs but no disability ☐ 2 = Disability but independent in usual daily activities ☐ 3 = Requires help for 1 or more daily activities but still mobile ☐ 4 = Dependent and needs help for mobility ☐ 5 = Bed bound

Barthel Index	*Tick appropriate number for each item*
Feeding	☐ 0 = unable ☐ 1 = needs help eg cutting, spreading ☐ 2 = independent
Bathing	☐ 0 = dependent ☐ 1 = independent
Grooming	☐ 0 = needs help with personal care ☐ 1 = independent face/hair/teeth/shaving (implements provided)
Dressing	☐ 0 = dependent ☐ 1 = needs help but can do about half unaided ☐ 2 = independent (including buttons, zips, laces etc)
Bowels	☐ 0 = incontinent (or needs to be given enemas) ☐ 1 = occasional accident ☐ 2 = continent
Bladder	☐ 0 = incontinent, or catheterised/sheath and unable to manage alone ☐ 1 = occasional accident ☐ 2 = continent
Toilet use	☐ 0 = dependent ☐ 1 = needs some help, but can do something alone ☐ 2 = independent (on and off, dressing, wiping)
Transfers (Bed to chair and back)	☐ 0 = unable, no sitting balance ☐ 1 = major help (1 or 2 people, physical), can sit ☐ 2 = minor help (physical or verbal) ☐ 3 = independent
Mobility (on level surfaces)	☐ 0 = immobile or < 10 m ☐ 1 = wheelchair independent, including corners, > 10 m ☐ 2 = walks with help of 1 person (verbal or physical) >10 m ☐ 3 = independent (but may use aid such as stick) > 10 m

Stairs	☐ 0 = unable ☐ 1 = need help (verbal, physical, carrying aid) ☐ 2 = independent

Frenchay activities index	*Tick appropriate number for each item*
1. Preparing meals	☐ 0 = never ☐ 1 = <1x/week ☐ 2 = 1-2x/week ☐ 3 = most days
2. Washing up	☐ 0 = never ☐ 1 = <1x/week ☐ 2 = 1-2x/week ☐ 3 = most days
3. Washing clothes	☐ 0 = never ☐ 1 = 1-2x/3 months ☐ 2 = 3-12x/3 months ☐ 3 = at least weekly
4. Light housework	☐ 0 = never ☐ 1 = 1-2x/3 months ☐ 2 = 3-12x/3 months ☐ 3 = at least weekly
5. Heavy housework	☐ 0 = never ☐ 1 = 1-2x/3 months ☐ 2 = 3-12x/3 months ☐ 3 = at least weekly
6. Local shopping	☐ 0 = never ☐ 1 = 1-2x/3 months ☐ 2 = 3-12x/3 months ☐ 3 = at least weekly
7. Social occasions	☐ 0 = never ☐ 1 = 1-2x/3 months ☐ 2 = 3-12x/3 months ☐ 3 = at least weekly
8. Walking outside > 15 mins	☐ 0 = never ☐ 1 = 1-2x/3 months ☐ 2 = 3-12x/3 months ☐ 3 = at least weekly
9. Actively pursuing hobby	☐ 0 = never ☐ 1 = 1-2x/3 months ☐ 2 = 3-12x/3 months ☐ 3 = at least weekly
10. Driving car/ going on bus	☐ 0 = never ☐ 1 = 1-2x/3 months ☐ 2 = 3-12x/3 months ☐ 3 = at least weekly

11. Travel outings/ car rides	☐ 0 = never
	☐ 1 = 1-2x/6 months
	☐ 2 = 3-12x/6 months
	☐ 3 = at least 2x weekly
12. Gardening	☐ 0 = never
	☐ 1 = light
	☐ 2 = moderate
	☐ 3 = all necessary
13. Household/car maintenance	☐ 0 = never
	☐ 1 = light
	☐ 2 = moderate
	☐ 3 = all necessary
14. Reading books	☐ 0 = none
	☐ 1 = 1 in 6 months
	☐ 2 = <1 per fortnight
	☐ 3 = >1 per fortnight
15. Gainful work	☐ 0 = none
	☐ 1 = up to 10 hr/week
	☐ 2 = 10-30 hr/week
	☐ 3 = >30 hr/week

Purpose Autonomy Mastery Connectedness (PAM-C)

☐ *Circle appropriate comment for each item*

1. My life has a clear sense of purpose.	Disagree strongly	Disagree	Agree	Agree strongly	N / A
2. I feel in control of my life.	Disagree strongly	Disagree	Agree	Agree strongly	N / A
3. I have the skills to make the most of my life.	Disagree strongly	Disagree	Agree	Agree strongly	N / A
4. I feel connected with the important people in my life.	Disagree strongly	Disagree	Agree	Agree strongly	N / A

PHQ-2 *Tick appropriate number for each item*

Over the past 2 weeks how often have you been bothered by any of the following Problems?	Not at all	Several days	More than half the days	Nearly every day
1. Little interest or pleasure in doing things	☐ 0	☐ 1	☐ 2	☐ 3
2. Feeling down, depressed or hopeless	☐ 0	☐ 1	☐ 2	☐ 3

Short Form 12 v2

This questionnaire asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

For each of the following questions, please mark an ☒ in the one box that best describes your answer.

1. **In general, would you say your health is:**

Excellent	Very good	Good	Fair	Poor
▼	▼	▼	▼	▼
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

2. **The following questions are about activities you might do during a typical day. Does <u>your health now limit you</u> in these activities? If so, how much?**

	Yes, limited a lot ▼	Yes, limited a little ▼	No, not limited at all ▼
a <u>Moderate activities</u>, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐ 1	☐ 2	☐ 3
b Climbing <u>several</u> flights of stairs	☐ 1	☐ 2	☐ 3

3. During the <u>past 4 weeks</u>, how much of the time have you had any of the following problems with your work or other regular daily activities <u>as a result of your physical health</u>?

	All of the time ▼	Most of the time ▼	Some of the time ▼	A little of the time ▼	None of the time ▼
a <u>Accomplished less</u> than you would like..................................	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b Were limited in the <u>kind</u> of work or other activities..............	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

4. During the <u>past 4 weeks</u>, how much of the time have you had any of the following problems with your work or other regular daily activities <u>as a result of any emotional problems</u> (such as feeling depressed or anxious)?

	All of the time ▼	Most of the time ▼	Some of the time ▼	A little of the time ▼	None of the time ▼
a <u>Accomplished less</u> than you would like..................................	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b Did work or other activities <u>less carefully than usual</u>	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

5. During the <u>past 4 weeks</u>, how much did <u>pain</u> interfere with your normal work (including both work outside the home and housework)?

Not at all ▼	A little bit ▼	Moderately ▼	Quite a bit ▼	Extremely ▼
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

6. **These questions are about how you feel and how things have been with you <u>during the past 4 weeks</u>. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the <u>past 4 weeks</u>…**

	All of the time ▼	Most of the time ▼	Some of the time ▼	A little of the time ▼	None of the time ▼
a Have you felt calm and peaceful?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b Did you have a lot of energy?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c Have you felt downhearted and depressed?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

7. **During the <u>past 4 weeks</u>, how much of the time has your <u>physical health or emotional problems</u> interfered with your social activities (like visiting with friends, relatives, etc.)?**

All of the time ▼	Most of the time ▼	Some of the time ▼	A little of the time ▼	None of the time ▼
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Below are some statements that people sometimes make when they talk about their health. Please indicate how much you agree or disagree with each statement as it applies to you personally by circling your answer. Your answers should be what is true for you and not just what you think others want you to say.

If the statement does not apply to you, circle **N/A.**

1.	When all is said and done, I am the person who is responsible for taking care of my health	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
2.	Taking an active role in my own health care is the most important thing that affects my health	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
3.	I am confident I can help prevent or reduce problems associated with my health	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
4.	I know what each of my prescribed medications do	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
5.	I am confident that I can tell whether I need to go to the doctor or whether I can take care of a health problem myself	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
6.	I am confident that I can tell a doctor concerns I have even when he or she does not ask	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
7.	I am confident that I can follow through on medical treatments I may need to do at home	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
8.	I understand my health problems and what causes them	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
9.	.I know what treatments are available for my health problems	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
10.	I have been able to maintain (keep up with) lifestyle changes, like eating right or exercising	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
11.	I know how to prevent problems with my health	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
12.	I am confident I can figure out solutions when new problems arise with my health	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
1 3.	I am confident that I can maintain lifestyle changes, like eating right and exercising, even during times of stress	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A

Taking Charge After Stroke – **TaCAS**   **STUDY ID** | | | |

AEs

Has the participant experienced any AE/SAEs since the previous visit?

No ☐ Yes ☐► Complete an AE form for each event.

RISK FACTOR ASSESSMENT

Weight	(kg)	
Heart Rate	(bpm)	
Pulse rhythm		☐ regular / ☐ not regular
Irregular rhythm and not on anti-anticoagulant		☐ Yes‡ / ☐ No
Atrial fibrillation (AF) previously diagnosed	☐ Yes / ☐ No	
Heart rate >120 bpm?	☐ Yes‡ / ☐ No	
Heart rate <40 bpm?	☐ Yes‡ / ☐ No	
Blood pressure (BP)	/ (mmHg)	Systolic <80 or >180 ☐ Yes‡ / ☐ No
Diabetes	☐ Yes / ☐ No	Treated: ☐ Yes / ☐ No
Current smoker	☐ Yes / ☐ No	
Initial:	Date:	

‡Discuss with participant notification to Primary Investigator

Outcome: _____

REHABILITATION AND SUPPORT (Self Reported)

Current rehab service involvement	☐ Yes / ☐ No
Hours of face-to-face rehab time in past week	
Current hours/ week home help (Paid)	
Current hours/ week personal cares (Paid)	
Current support adequate	☐ Yes / ☐ No
Carers trained by rehab service	☐ Yes / ☐ No
Unpaid carers: roughly how much per week does it cost your unpaid carer/s to support you (eg lost wages, transport)?	/ week
Initial:	Date:

TaCAS 2 (second intervention) visit Worksheet- Version 3.3, 25 Feb 2016

Taking Charge After Stroke – **TaCAS**

STUDY ID ⬚ ⬚ ⬚

WORK (Self-reported)

Have there been any changes to the participant's working situation since the previous visit?		☐ Yes / ☐ No
If yes:	Has the participant started working?	☐ Yes / ☐ No / ☐ n/a
	Has the participant stopped working?	☐ Yes / ☐ No / ☐ n/a
	Has the participant increased work hours?	☐ Yes / ☐ No / ☐ n/a
	Has the participant decreased work hours?	☐ Yes / ☐ No / ☐ n/a
Average take-home pay per week since previous visit?		
Initial:		Date:

INTERVENTION COMPLETED

TaCAS 2 (second intervention)   ☐

How many support people present: 0 / 1 / 2 / 3 / 4 / 5 / 6 / 7 / 8 / 9 / 10 / >10

Was one of these people your spouse/partner: ☐ Yes / ☐ No

Intervention Completed by:

Initial: Date:

ARRANGEMENTS FOR 6 MONTH FOLLOW-UP (ALL PARTICIPANTS):

Anticipated date**:_____/_____/_____

Preferred time:_____:_____

** must be six months post stroke +/- 14 days

Notification sent to "6-m follow-up Researcher":   ☐ Yes / ☐ No

Initial: Date:

Taking Charge After Stroke – **TaCAS**

Research Clinician comment:

What went well during this session?

_____

_____

What did not go well?

_____

_____

What "stand out" comments were there from the participant?

_____

_____

Visit completed by:

Name:	Sign:	Date:
Name:	Sign:	Date:

TaCAS 6-month assessment form

TaCAS 6 month assessment *(by blinded assessor)*

Participant Initials:

DATE: _____ / _____ / _____

(6 months after stroke +/- 14 days)

Change of status if applicable – choose one:	
Admitted to hospital □	Admission date and reason:
Moved overseas □	Departure date and date of return:
New Address	
Contact phone numbers	1. ( )
	2. ( )
Alternate contact name and address	
Alternate contact phone	1. ( )
	2. ( )

Taking Charge After Stroke – TaCAS

ASSESSMENTS

Modified Rankin Score

Please tick the best answer applicable to you TODAY.

1. Are you fully recovered from your stroke?

☐ Yes   ☐ No (go to Q2)

2. Are you disabled in any way from your stroke?

☐ No   ☐ Yes (go to Q3)

3. Do you need help from another person with usual, day-to-day activities?

☐ No   ☐ Yes (go to Q4)

***4.* Are you able to walk independently?** *(Can use aids, but able to carry them up and down stairs)*

☐ Yes   ☐ No

Barthel Index

Please choose the best answer applicable to you TODAY (in the last 24-48 hours).
How capable are you at doing the following activities?

1. Feeding yourself

☐ Unable

☐ Need help, e.g. cutting, spreading jam

☐ Independent (if food provided within reach)

2. Bathing (or showering) yourself

☐ Dependent   ☐ Independent

Independent = must get in and out unsupervised without help and wash self

3. Grooming *

☐ Need help with personal care   ☐ Independent

Independent = with face/hair/teeth/shaving (implements provided)

4. Dressing yourself

☐   Dependent

☐   Need help but can do about half unaided

☐   Independent (including buttons, zips, laces etc.)

5. Bowels

☐   Incontinent (or requiring caregiver-administered enemas)

☐   Occasional accident

☐   Continent

6. Bladder

☐   Incontinent, or catheterised/sheath, unable to manage alone

☐   Occasional accident

☐   Continent

7. Toilet use

☐   Dependent

☐   Need some help, but can do something alone

☐   Independent (on and off, dressing, wiping)

Independent = should be able to reach toilet / commode, undress sufficiently, clean self, dress and leave

8. Transfers (bed to chair and back)

☐   Unable - no sitting balance

☐   Major help (one or two people assisting, physical), can sit

☐   Minor help (one person easily assisting OR need supervision for safety)

☐   Independent

9. Mobility (on level surfaces)

☐   Immobile

☐   Wheelchair independent, including corners, >10 metres

☐   Walks with help of one person (verbal or physical), >10 metres

☐   Independent (may use any aid, e.g. stick) > 10 metres

10. Walking on stairs

☐   Unable

☐   Need help (verbal, physical, carrying walking aid)

☐   Independent up and down

Independent = must carry any walking aid used

Frenchay Activities Index

In the last THREE MONTHS how often would you have undertaken:

	Tick appropriate number for each item
1. Preparing meals *Need to play a substantial part in the organization, preparation and cooking of main meal. Not just making snacks or reheating prepared food.*	☐ 0 = never ☐ 1 = less than once per week ☐ 2 = 1-2 times per week ☐ 3 = most days
2. Washing up *Must do it all or share equally, including washing, wiping and putting away.*	☐ 0 = never ☐ 1 = less than once per week ☐ 2 = 1-2 times per week ☐ 3 = most days
3. Washing clothes *Organization of washing and drying clothes, whether in washing machine, or by hand or at laundromat. Sharing task equally, e.g. loading, unloading, hanging, folding.*	☐ 0 = never ☐ 1 = 1-2 times in 3 months ☐ 2 = 3-12 times in 3 months ☐ 3 = at least weekly
4. Light housework *e.g. dusting, polishing, ironing, tidying small objects*	☐ 0 = never ☐ 1 = 1-2 times in 3 months ☐ 2 = 3-12 times in 3 months ☐ 3 = at least weekly

5. Heavy housework *All heavier housework including changing beds, cleaning floors, fires and windows, vacuuming, moving chairs, etc.*	☐ 0 = never ☐ 1 = 1-2 times in 3 months ☐ 2 = 3-12 times in 3 months ☐ 3 = at least weekly
6. Local shopping *Playing a substantial role in organizing and buying groceries, whether small or large amounts. Must go to the shop and not just push a cart. Can include collection of pension or going to the Post Office.*	☐ 0 = never ☐ 1 = 1-2 times in 3 months ☐ 2 = 3-12 times in 3 months ☐ 3 = at least weekly
7. Social occasions *Going out to clubs, church activities, cinema, theatre, drinking, to dinner with friends, etc. You may be transported there, provided you take an active part once arrived. Includes social activities at home, initiated by the yourself, e.g. visits from family or friends not where main purpose is to provide care.*	☐ 0 = never ☐ 1 = 1-2 times in 3 months ☐ 2 = 3-12 times in 3 months ☐ 3 = at least weekly
8. Walking outside > 15 mins *Sustained walking for at least 15 minutes (allowed short stops for breath). About one mile (1.5km). Can include walking to do shopping, provided walks far enough.*	☐ 0 = never ☐ 1 = 1-2 times in 3 months ☐ 2 = 3-12 times in 3 months ☐ 3 = at least weekly
9. Actively pursuing hobby *Must require some 'active' participation and thought, e.g. propagating or caring for houseplants, knitting, painting, games, sports (not just watching sport on television). Can be mental activities, e.g. reading specialist magazines, doing the stocks and shares or window shopping for pleasure.*	☐ 0 = never ☐ 1 = 1-2 times in 3 months ☐ 2 = 3-12 times in 3 months ☐ 3 = at least weekly
10. Driving car/ going on bus *Must drive a car (not just be a passenger), or get to a bus/coach and travel on it independently.*	☐ 0 = never ☐ 1 = 1-2 times in 3 months ☐ 2 = 3-12 times in 3 months ☐ 3 = at least weekly
11. Travel outings/ car rides *Coach or rail trips or car rides to some place for pleasure. Not for a routine 'social outing' (i.e. shopping, going to local friends). Must involve some organization and decision-making by you. Excludes trips organized passively by institutions unless you exercise choice on whether to go. The common factor is travel for pleasure. Holidays within the six months are divided into days per month e.g. a 7-day holiday equals 1 or 2 days per month.*	☐ 0 = never ☐ 1 = 1-2 times in 6 months ☐ 2 = 3-12 times in 6 months ☐ 3 = at least weekly
12. Gardening *Light = occasional weeding or sweeping paths* *Moderate = regular weeding, raking, pruning, etc.* *Heavy = all necessary work including heavy digging.*	☐ 0 = never ☐ 1 = light ☐ 2 = moderate ☐ 3 = all necessary
13. Household/car maintenance *Light = repairing small items, replacing lamp light bulb or plug.* *Moderate = spring cleaning, hanging a picture, routine car maintenance.* *Heavy = painting/decorating, most necessary household/car maintenance.*	☐ 0 = never ☐ 1 = light ☐ 2 = moderate ☐ 3 = all necessary
14. Reading books *Must be full-length books, not periodicals, magazines or newspapers. Can be talking books.*	☐ 0 = none ☐ 1 = Once in 6 months ☐ 2 = less than once per fortnight ☐ 3 = More than once per fortnight

15. Gainful work *Work for which you are paid, not voluntary work. The time worked should be averaged out over six months. For example, one month working for 18 hours/week over the six-month period would be scored as 'up to 10 hours/week'.*	☐ 0 = none ☐ 1 = up to 10 hours a week ☐ 2 = 10-30 hours a week ☐ 3 = Over 30 hours a week

Purpose Autonomy Mastery Connectedness (PAM-C)

Circle appropriate comment for each item

1. My life has a clear sense of purpose.	Disagree strongly	Disagree	Agree	Agree strongly	N / A
2. I feel in control of my life.	Disagree strongly	Disagree	Agree	Agree strongly	N / A
3. I have the skills to make the most of my life.	Disagree strongly	Disagree	Agree	Agree strongly	N / A
4. I feel connected with the important people in my life.	Disagree strongly	Disagree	Agree	Agree strongly	N / A

PHQ-2 *Tick appropriate number for each item*

Over the past TWO WEEKS how often have you been bothered by any of the following Problems?	Not at all	Several days	More than half the days	Nearly every day
1. Little interest or pleasure in doing things	☐ 0	☐ 1	☐ 2	☐ 3
2. Feeling down, depressed or hopeless	☐ 0	☐ 1	☐ 2	☐ 3

Taking Charge After Stroke – **TaCAS**

EQ-5D-5L *Under each heading, please tick the ONE box that best describes your health TODAY*

(New Zealand (English) © 2010 EuroQol Group EQ-5D™ is a trade mark of the EuroQol Group)

MOBILITY

I have no problems in walking about ☐

I have slight problems in walking about ☐

I have moderate problems in walking about ☐

I have severe problems in walking about ☐

I am unable to walk about ☐

SELF-CARE

I have no problems washing or dressing myself ☐

I have slight problems washing or dressing myself ☐

I have moderate problems washing or dressing myself ☐

I have severe problems washing or dressing myself ☐

I am unable to wash or dress myself ☐

USUAL ACTIVITIES *(e.g. work, study, housework, family or leisure activities)*

I have no problems doing my usual activities ☐

I have slight problems doing my usual activities ☐

I have moderate problems doing my usual activities ☐

I have severe problems doing my usual activities ☐

I am unable to do my usual activities ☐

PAIN / DISCOMFORT

I have no pain or discomfort ☐

I have slight pain or discomfort ☐

I have moderate pain or discomfort ☐

I have severe pain or discomfort ☐

I have extreme pain or discomfort ☐

ANXIETY / DEPRESSION

I am not anxious or depressed ☐

I am slightly anxious or depressed ☐

I am moderately anxious or depressed ☐

I am severely anxious or depressed ☐

I am extremely anxious or depressed ☐

Taking Charge After Stroke – TaCAS

The best health you
can imagine

- We would like to know how good or bad your health is TODAY.

- This scale is numbered from 0 to 100.

- 100 means the <u>best</u> health you can imagine. 0 means the <u>worst</u> health you can imagine.

- Mark an X on the scale to indicate how your health is TODAY.

YOUR HEALTH TODAY =

100
95
90
85
80
75
70
65
60
55
50
45
40
35
30
25
20
15
10
5
0

The worst health
you can imagine

Taking Charge After Stroke – **TaCAS**

SF12v2

1. **In general, would you say your health is:**

Excellent	Very good	Good	Fair	Poor
▼	▼	▼	▼	▼
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

2. **The following questions are about activities you might do during a typical day. Does <u>your health now limit you</u> in these activities? If so, how much?**

	Yes, limited a lot	Yes, limited a little	No, not limited at all
	▼	▼	▼
a <u>Moderate activities</u>, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐ 1	☐ 2	☐ 3
b Climbing <u>several</u> flights of stairs	☐ 1	☐ 2	☐ 3

3. **During the <u>past 4 weeks</u>, how much of the time have you had any of the following problems with your work or other regular daily activities <u>as a result of your physical health</u>?**

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
	▼	▼	▼	▼	▼
a <u>Accomplished less</u> than you would like	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b Were limited in the <u>kind</u> of work or other activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

4. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

		All of the time ▼	Most of the time ▼	Some of the time ▼	A little of the time ▼	None of the time ▼
a	Accomplished less than you would like......................................	☐1	☐2	☐3	☐4	☐5
b	Did work or other activities less carefully than usual	☐1	☐2	☐3	☐4	☐5

5. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

Not at all ▼	A little bit ▼	Moderately ▼	Quite a bit ▼	Extremely ▼
1	2	3	4	5
☐	☐	☐	☐	☐

6. **These questions are about how you feel and how things have been with you <u>during the past 4 weeks</u>. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the <u>past 4 weeks</u>…**

		All of the time	Most of the time	Some of the time	A little of the time	None of the time
a	Have you felt calm and peaceful?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b	Did you have a lot of energy?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c	Have you felt downhearted and depressed?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

During the <u>past 4 weeks</u>, how much of the time has your <u>physical health or emotional problems</u> interfered with your social activities (like visiting with friends, relatives, etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

![Insignia Health logo]

Below are some statements that people sometimes make when they talk about their health. Please indicate how much you agree or disagree with each statement as it applies to you personally by circling your answer. Your answers should be what is true for you and not just what you think others want you to say.

If the statement does not apply to you, circle N/A.

1.	When all is said and done, I am the person who is responsible for taking care of my health	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
2.	Taking an active role in my own health care is the most important thing that affects my health	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
3.	I am confident I can help prevent or reduce problems associated with my health	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
4.	I know what each of my prescribed medications do	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
5.	I am confident that I can tell whether I need to go to the doctor or whether I can take care of a health problem myself	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
6.	I am confident that I can tell a doctor concerns I have even when he or she does not ask	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
7.	I am confident that I can follow through on medical treatments I may need to do at home	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
8.	I understand my health problems and what causes them	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
9.	I know what treatments are available for my health problems	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
10.	I have been able to maintain (keep up with) lifestyle changes, like eating right or exercising	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
11.	I know how to prevent problems with my health	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
12.	I am confident I can figure out solutions when new problems arise with my health	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
13.	I am confident that I can maintain lifestyle changes, like eating right and exercising, even during times of stress	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A

Taking Charge After Stroke – **TaCAS**

CURRENT MEDICATIONS

Please identify whether or not you are CURRENTLY taking the following medicines:

Fluoxetine *(antidepressant)*	☐ Yes / ☐ No
Anti-hypertensive *(eg: cilazapril, quinapril, enalapril, candesartan, losartan, felodipine, amlopidine, diltiazem, bendrofluazide, frusemide, carvedilol, metoprolol, atenolol)*	☐ Yes ☐ No
Anti-coagulant	☐ Yes – I take warfarin ☐ Yes – I take dabigatran ☐ No
Anti-platelet	☐ Yes – I take clopidogrel ☐ Yes – I take aspirin ☐ Yes – I take both aspirin and clopidogrel ☐ No
Cholesterol lowering medication *(a statin, usually atorvastatin or simvastatin, ezetimibe, bezafibrate or gemfibrozil)*	☐ Yes / ☐ No

REHABILITATION AND SUPPORT (Self-Reported)

Did you have a key support person during this time since your stroke?	☐ Yes / ☐ No
If yes, how is this person related to you?	
If yes, roughly how much per week does it cost your unpaid carer/s to support you (eg lost wages, transport)?	/ week
Current rehab service involvement (Physiotherapist, occupational therapist, speech language therapist, etc.)	☐ Yes / ☐ No
Hours of face-to-face rehab time in past month	
How many hours per week of home help do you currently receive? (e.g. housework)	
How many hours per week of personal cares do you currently receive? (e.g. shower assistance)	
Current support adequate?	☐ Yes / ☐ No

Taking Charge After Stroke – **TaCAS**

STUDY ID ☐ ☐ ☐ ☐

WORK

The following questions will help us assess the financial impact of the stroke, and will be useful in an analysis on how cost-effective the Take Charge session is.

Are you currently in paid employment?	☐ Yes / ☐ No
If yes, what is your current average take-home pay per week?	/ week ☐ I do not wish to disclose

Caregiver Strain Index at six months

The following questions should be completed by your next-of-kin / main caregiver. These questions measure the effect of your stroke on their lives. They should tick "YES" for the statements which they agree with, and "NO" for those with which they disagree.

	Yes	No
Sleep is disturbed (e.g., because_____is in and out of bed or wanders around at night)		
It is inconvenient (e.g., because helping takes so much time or it's a long drive over to help)		
It is a physical strain (e.g., because of lifting in and out of a chair; effort or concentration is required)		
It is confining (e.g., helping restricts free time or cannot go visiting)		
There have been family adjustments (e.g., because helping has disrupted routine; there has been no privacy)		
There have been changes in personal plans (e.g., had to turn down a job; could not go on vacation)		
There have been other demands on my time (e.g., from other family members)		
There have been emotional adjustments (e.g., because of severe arguments)		
Some behaviours are upsetting (e.g., because of incontinence;_____has trouble remembering things; or_____accuses people of taking things)		
It is upsetting to find_____has changed so much from his/her former self (e.g., he/she is a different person than he/she used to be)		
There have been work adjustments (e.g., because of having to take time off)		
It is a financial strain		
Feeling completely overwhelmed (e.g., because of worry about_____; concerns about how you will manage)		
TOTAL SCORE		

Taking Charge After Stroke – **TaCAS**   **STUDY ID**

Thank you for completing this six-month follow-up questionnaire.

Please post it back to us in the stamped envelope at your earliest convenience if you wish. Please phone us at 04 8050147 if you have any questions regarding filling out this questionnaire.

If you prefer to have this questionnaire conducted over the phone, please let us know this when we telephone you in a week. We can conduct the questionnaire at the time or arrange a more convenient time for you.

Telephone interview completed by:

Name: Sign: Date:

TaCAS 12 month assessment form

TaCAS 12m Final Home Visit Assessment *(by blinded assessor)*

Participant Initials: ☐☐☐   **DATE:** ____ / ____ / _____

Change of status if applicable – choose one:

Admitted to hospital	Admission date and reason:
Move overseas	Departure date and date of return:
New Address	
Contact phone numbers	1. ( )
	2. ( )
Alternate contact name and address	
Alternate contact phone	1. ( )
	2. ( )

Taking Charge After Stroke – **TaCAS**

ASSESSMENTS

Modified Rankin Score

Please tick the best answer applicable to you TODAY.

1. **Are you fully recovered from your stroke?**

   ☐ Yes   ☐ No (go to Q2)

2. **Are you disabled in any way from your stroke?**

   ☐ No   ☐ Yes (go to Q3)

3. **Do you need help from another person with usual, day-to-day activities?**

   ☐ No   ☐ Yes (go to Q4)

4. ***Are you able to walk independently?*** *(Can use aids, but able to carry them up and down stairs)*

   ☐ Yes   ☐ No

Barthel Index

Please choose the best answer applicable to you TODAY (in the last 24-48 hours).
How capable are you at doing the following activities?

1. Feeding yourself

   ☐   Unable

   ☐   Need help, e.g. cutting, spreading jam

   ☐   Independent (if food provided within reach)

2. Bathing (or showering) yourself

   ☐   Dependent   ☐   Independent

   Independent = must get in and out unsupervised without help and wash self

3. Grooming *

   ☐   Need help with personal care   ☐   Independent

   Independent = with face/hair/teeth/shaving (implements provided)

4. Dressing yourself

☐   Dependent

☐   Need help but can do about half unaided

☐   Independent (including buttons, zips, laces etc.)

5. Bowels

☐   Incontinent (or requiring caregiver-administered enemas)

☐   Occasional accident

☐   Continent

6. Bladder

☐   Incontinent, or catheterised/sheath, unable to manage alone

☐   Occasional accident

☐   Continent

7. Toilet use

☐   Dependent

☐   Need some help, but can do something alone

☐   Independent (on and off, dressing, wiping)

Independent = should be able to reach toilet / commode, undress sufficiently, clean self, dress and leave

8. Transfers (bed to chair and back)

☐   Unable - no sitting balance

☐   Major help (one or two people assisting, physical), can sit

☐   Minor help (one person easily assisting OR need supervision for safety)

☐   Independent

9. Mobility (on level surfaces)

☐   Immobile

Taking Charge After Stroke – **TaCAS** **STUDY ID** ☐☐☐☐

☐ Wheelchair independent, including corners, >10 metres

☐ Walks with help of one person (verbal or physical), >10 metres

☐ Independent (may use any aid, e.g. stick) > 10 metres

10. Walking on stairs

☐ Unable

☐ Need help (verbal, physical, carrying walking aid)

☐ Independent up and down

Independent = must carry any walking aid used

Frenchay Activities Index

In the last THREE MONTHS how often would you have undertaken:

	Tick appropriate number for each item
1. Preparing meals *Need to play a substantial part in the organization, preparation and cooking of main meal. Not just making snacks or reheating prepared food.*	☐ 0 = never ☐ 1 = less than once per week ☐ 2 = 1-2 times per week ☐ 3 = most days
2. Washing up *Organization of washing and drying clothes, whether in washing machine, or by hand or at laundromat. Sharing task equally, e.g. loading, unloading, hanging, folding.*	☐ 0 = never ☐ 1 = less than once per week ☐ 2 = 1-2 times per week ☐ 3 = most days
3. Washing clothes *Organization of washing and drying clothes, whether in washing machine, or by hand or at laundromat. Sharing task equally, e.g. loading, unloading, hanging, folding.*	☐ 0 = never ☐ 1 = 1-2 times in 3 months ☐ 2 = 3-12 times in 3 months ☐ 3 = at least weekly
4. Light housework *e.g. dusting, polishing, ironing, tidying small objects*	☐ 0 = never ☐ 1 = 1-2 times in 3 months ☐ 2 = 3-12 times in 3 months ☐ 3 = at least weekly
5. Heavy housework *All heavier housework including changing beds, cleaning floors, fires and windows, vacuuming, moving chairs, etc.*	☐ 0 = never ☐ 1 = 1-2 times in 3 months ☐ 2 = 3-12 times in 3 months ☐ 3 = at least weekly

6. Local shopping *Playing a substantial role in organizing and buying groceries, whether small or large amounts. Must go to the shop and not just push a cart. Can include collection of pension or going to the Post Office.*	☐ 0 = never ☐ 1 = 1-2 times in 3 months ☐ 2 = 3-12 times in 3 months ☐ 3 = at least weekly
7. Social occasions *Going out to clubs, church activities, cinema, theatre, drinking, to dinner with friends, etc. You may be transported there, provided you take an active part once arrived. Includes social activities at home, initiated by the yourself, e.g. visits from family or friends not where main purpose is to provide care.*	☐ 0 = never ☐ 1 = 1-2 times in 3 months ☐ 2 = 3-12 times in 3 months ☐ 3 = at least weekly
8. Walking outside > 15 mins *Sustained walking for at least 15 minutes (allowed short stops for breath). About one mile (1.5km). Can include walking to do shopping, provided walks far enough.*	☐ 0 = never ☐ 1 = 1-2 times in 3 months ☐ 2 = 3-12 times in 3 months ☐ 3 = at least weekly
9. Actively pursuing hobby *Must require some 'active' participation and thought, e.g. propagating or caring for houseplants, knitting, painting, games, sports (not just watching sport on television). Can be mental activities, e.g. reading specialist magazines, doing the stocks and shares or window shopping for pleasure.*	☐ 0 = never ☐ 1 = 1-2 times in 3 months ☐ 2 = 3-12 times in 3 months ☐ 3 = at least weekly
10. Driving car/ going on bus *Must drive a car (not just be a passenger), or get to a bus/coach and travel on it independently.*	☐ 0 = never ☐ 1 = 1-2 times in 3 months ☐ 2 = 3-12 times in 3 months ☐ 3 = at least weekly
11. Travel outings/ car rides *Coach or rail trips or car rides to some place for pleasure. Not for a routine 'social outing' (i.e. shopping, going to local friends). Must involve some organization and decision-making by you. Excludes trips organized passively by institutions unless you exercise choice on whether to go. The common factor is travel for pleasure. Holidays within the six months are divided into days per month e.g. a 7-day holiday equals 1 or 2 days per month.*	☐ 0 = never ☐ 1 = 1-2 times in 6 months ☐ 2 = 3-12 times in 6 months ☐ 3 = at least weekly
12. Gardening *Light = occasional weeding or sweeping paths* *Moderate = regular weeding, raking, pruning, etc.* *Heavy = all necessary work including heavy digging.*	☐ 0 = never ☐ 1 = light ☐ 2 = moderate ☐ 3 = all necessary
13. Household/car maintenance *Light = repairing small items, replacing lamp light bulb or plug.* *Moderate = spring cleaning, hanging a picture, routine car maintenance.* *Heavy = painting/decorating, most necessary household/car maintenance.*	☐ 0 = never ☐ 1 = light ☐ 2 = moderate ☐ 3 = all necessary
14. Reading books *Must be full-length books, not periodicals, magazines or newspapers. Can be talking books.*	☐ 0 = none ☐ 1 = Once in 6 months ☐ 2 = less than once per fortnight ☐ 3 = More than once per fortnight
15. Gainful work *Work for which you are paid, not voluntary work. The time worked should be averaged out over six months. For example, one month working for 18 hours/week over the six-month period would be scored as 'up to 10 hours/week'.*	☐ 0 = none ☐ 1 = up to 10 hours a week ☐ 2 = 10-30 hours a week ☐ 3 = Over 30 hours a week

Taking Charge After Stroke – TaCAS

Purpose Autonomy Mastery Connectedness (PAM-C)

Circle appropriate comment for each item

1. My life has a clear sense of purpose.	Disagree strongly	Disagree	Agree	Agree strongly	N / A
2. I feel in control of my life.	Disagree strongly	Disagree	Agree	Agree strongly	N / A
3. I have the skills to make the most of my life.	Disagree strongly	Disagree	Agree	Agree strongly	N / A
4. I feel connected with the important people in my life.	Disagree strongly	Disagree	Agree	Agree strongly	N / A

PHQ-2 *Tick appropriate number for each item*

Over the past TWO WEEKS how often have you been bothered by any of the following Problems?	Not at all	Several days	More than half the days	Nearly every day
1. Little interest or pleasure in doing things	☐ 0	☐ 1	☐ 2	☐ 3
2. Feeling down, depressed or hopeless	☐ 0	☐ 1	☐ 2	☐ 3

EQ-5D-5L *Under each heading, please tick the ONE box that best describes your health TODAY*

(New Zealand (English) © 2010 EuroQol Group EQ-5D™ is a trade mark of the EuroQol Group)

MOBILITY

I have no problems in walking about ☐

I have slight problems in walking about ☐

I have moderate problems in walking about ☐

I have severe problems in walking about ☐

I am unable to walk about ☐

SELF-CARE

I have no problems washing or dressing myself ☐

I have slight problems washing or dressing myself ☐

I have moderate problems washing or dressing myself ☐

I have severe problems washing or dressing myself ☐

I am unable to wash or dress myself ☐

USUAL ACTIVITIES *(e.g. work, study, housework, family or leisure activities)*

I have no problems doing my usual activities ☐

I have slight problems doing my usual activities ☐

I have moderate problems doing my usual activities ☐

I have severe problems doing my usual activities ☐

I am unable to do my usual activities ☐

PAIN / DISCOMFORT

I have no pain or discomfort ☐

I have slight pain or discomfort ☐

I have moderate pain or discomfort ☐

I have severe pain or discomfort ☐

I have extreme pain or discomfort ☐

ANXIETY / DEPRESSION

I am not anxious or depressed ☐

I am slightly anxious or depressed ☐

I am moderately anxious or depressed ☐

I am severely anxious or depressed ☐

I am extremely anxious or depressed ☐

Taking Charge After Stroke – **TaCAS**

We would like to know how good or bad your health is TODAY.

This scale is numbered from 0 to 100.

100 means the <u>best</u> health you can imagine. 0 means the <u>worst</u> health you can imagine.

Mark an X on the scale to indicate how your health is TODAY.

Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY = ☐

The best health you can imagine

100
95
90
85
80
75
70
65
60
55
50
45
40
35
30
25
20
15
10
5
0

The worst health you can imagine

Taking Charge After Stroke – **TaCAS**

SF36v2

1. **In general, would you say your health is:**

Excellent	Very good	Good	Fair	Poor
▼	▼	▼	▼	▼
☐1	☐2	☐3	☐4	☐5

2. <u>**Compared to 6 months ago**</u>**, how would you rate your health in general** <u>**now**</u>**?**

Much better now than 6 months ago	Somewhat better now than 6 months ago	About the same as 6 months ago	Somewhat worse now than 6 months ago	Much worse now than 6 months ago
▼	▼	▼	▼	▼
☐1	☐2	☐3	☐4	☐5

3. **The following questions are about activities you might do during a typical day. Does** <u>**your health now limit you**</u> **in these activities? If so, how much?**

	Yes, limited a lot ▼	Yes, limited a little ▼	No, not limited at all ▼
a <u>Vigorous activities</u>, such as running, lifting heavy objects, participating in strenuous sports	☐1	☐2	☐3
b <u>Moderate activities</u>, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐1	☐2	☐3
c Lifting or carrying groceries	☐1	☐2	☐3
d Climbing <u>several</u> flights of stairs	☐1	☐2	☐3
e Climbing <u>one</u> flight of stairs	☐1	☐2	☐3
f Bending, kneeling, or stooping	☐1	☐2	☐3
g Walking <u>more than a kilometre</u>	☐1	☐2	☐3
h Walking <u>several hundred metres</u>	☐1	☐2	☐3
i Walking <u>one hundred metres</u>	☐1	☐2	☐3
j Bathing or dressing yourself	☐1	☐2	☐3

4.   During the <u>past 4 weeks</u>, how much of the time have you had any of the following problems with your work or other regular daily activities <u>as a result of your physical health</u>?

	All of the time ▼	Most of the time ▼	Some of the time ▼	A little of the time ▼	None of the time ▼
a Cut down on the <u>amount of time</u> you spent on work or other activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b <u>Accomplished less</u> than you would like	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c Were limited in the <u>kind</u> of work or other activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
d Had <u>difficulty</u> performing the work or other activities (for example, it took extra effort)	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

5.   During the <u>past 4 weeks</u>, how much of the time have you had any of the following problems with your work or other regular daily activities <u>as a result of any emotional problems</u> (such as feeling depressed or anxious)?

	All of the time ▼	Most of the time ▼	Some of the time ▼	A little of the time ▼	None of the time ▼
a Cut down on the <u>amount of time</u> you spent on work or other activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b <u>Accomplished less</u> than you would like	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c Did work or other activities <u>less carefully than usual</u>	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

6.   During the <u>past 4 weeks</u>, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours, or groups?

Not at all ▼	Slightly ▼	Moderately ▼	Quite a bit ▼	Extremely ▼
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

7. **How much <u>bodily</u> pain have you had during the <u>past 4 weeks</u>?**

None	Very mild	Mild	Moderate	Severe	Very severe
▼	▼	▼	▼	▼	▼
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

8. **During the <u>past 4 weeks</u>, how much did <u>pain</u> interfere with your normal work (including both work outside the home and housework)?**

Not at all	A little bit	Moderately	Quite a bit	Extremely
▼	▼	▼	▼	▼
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

9. **These questions are about how you feel and how things have been with you <u>during the past 4 weeks</u>. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the <u>past 4 weeks</u>…**

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
	▼	▼	▼	▼	▼
a Did you feel full of life?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b Have you been very nervous?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c Have you felt so down in the dumps that nothing could cheer you up?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
d Have you felt calm and peaceful?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
e Did you have a lot of energy?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
f Have you felt downhearted and depressed?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
g Did you feel worn out?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
h Have you been happy?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
i Did you feel tired?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Taking Charge After Stroke – TaCAS   **STUDY ID** ☐☐☐☐

10. During the <u>past 4 weeks,</u> how much of the time has your <u>physical health or emotional problems</u> interfered with your social activities (like visiting with friends, relatives, etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
▼	▼	▼	▼	▼
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

11. How TRUE or FALSE is <u>each</u> of the following statements for you?

	Definitely true ▼	Mostly true ▼	Don't know ▼	Mostly false ▼	Definitely false ▼
a I seem to get sick a little easier than other people	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b I am as healthy as anybody I know	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c I expect my health to get worse	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
d My health is excellent	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Below are some statements that people sometimes make when they talk about their health. Please indicate how much you agree or disagree with each statement as it applies to you personally by circling your answer. Your answers should be what is true for you and not just what you think others want you to say.

If the statement does not apply to you, circle N/A.

1.	When all is said and done, I am the person who is responsible for taking care of my health	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
2.	Taking an active role in my own health care is the most important thing that affects my health	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
3.	I am confident I can help prevent or reduce problems associated with my health	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
4.	I know what each of my prescribed medications do	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
5.	I am confident that I can tell whether I need to go to the doctor or whether I can take care of a health problem myself	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
6.	I am confident that I can tell a doctor concerns I have even when he or she does not ask	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
7.	I am confident that I can follow through on medical treatments I may need to do at home	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
8.	I understand my health problems and what causes them	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
9.	I know what treatments are available for my health problems	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
10.	I have been able to maintain (keep up with) lifestyle changes, like eating right or exercising	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
11.	I know how to prevent problems with my health	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
12.	I am confident I can figure out solutions when new problems arise with my health	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
13.	I am confident that I can maintain lifestyle changes, like eating right and exercising, even during times of stress	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A

Initials: _____

Taking Charge After Stroke – **TaCAS**

STUDY ID ☐ ☐ ☐

CURRENT MEDICATIONS

Fluoxetine *(antidepressant)*	☐ Yes / ☐ No
Anti-hypertensive *(eg: cilazapril, quinapril, enalapril, candesartan, Losartan, felodipine, amlopidine, diltiazem, bendrofluazide, frusemide, carvedilol, metoprolol, atenolol)*	☐ Yes / ☐ No
Anti-coagulant	☐ Yes / ☐ No
(*Select*): ☐ warfarin / ☐ dabigatran	
Anti-platelet	☐ Yes / ☐ No
(*Select*): ☐ clopidogrel / ☐ aspirin	
Cholesterol lowering medication *(a statin, usually atorvastatin or simvastatin, ezetimibe, bezafibrate or gemfibrozil)*	☐ Yes / ☐ No

Medication Adherence Questionnaire	
Do you ever forget to take your medicine?	☐ Yes / ☐ No
Are you careless at times about taking your medicine?	☐ Yes / ☐ No
When you feel better do you sometimes stop taking your medicine?	☐ Yes / ☐ No
Sometimes if you feel worse when you take the medicine, do you stop taking it?	☐ Yes / ☐ No
If Yes to 2+ questions, which medication(s) do you tend to miss, and why?	☐ Fluoxetine ☐ Anti-Hypertensive ☐ Anti-Coagulant ☐ Anti-Platelet ☐ Cholesterol-Lowering ☐ Other
In the past 2 weeks, how many days would you have missed your medication?	☐ No missed doses ☐ Largely compliant (1-2 days missed) ☐ Somewhat compliant (3-7 days missed) ☐ Not compliant (> 7 days missed)
Please specify:	
Initial:	Date:

RISK FACTOR ASSESSMENT

Weight	(kg)
Heart Rate	(bpm)
Pulse rhythm	☐ regular / ☐ not regular

Taking Charge After Stroke – TaCAS

STUDY ID [ ][ ][ ]

Irregular rhythm and not on anti-anticoagulant		☐ Yes‡ / ☐ No
Atrial fibrillation (AF) previously diagnosed	☐ Yes / ☐ No	
Heart rate >120 bpm?	☐ Yes‡ / ☐ No	
Heart rate <40 bpm?	☐ Yes‡ / ☐ No	
Blood pressure (BP)	/ (mmHg)	Systolic <80 or >180 ☐ Yes‡ / ☐ No
Diabetes	☐ Yes / ☐ No	Treated: ☐ Yes / ☐ No
Current smoker	☐ Yes / ☐ No	
Initial:	Date:	

‡Discuss with participant notification to Primary Investigator

Outcome: _____

REHABILITATION AND SUPPORT (Self Reported)

Did you have a key support person during this time since your stroke?	☐ Yes / ☐ No
If yes, how is this person related to you?	
If yes, roughly how much per week does it cost your unpaid carer/s to support you (eg lost wages, transport)?	/ week
Current rehab service involvement	☐ Yes / ☐ N o
Hours of face-to-face rehab time in past month	
Current hours/ week home help	
Current hours/ week personal cares	
Current support adequate	☐ Yes / ☐ No
Carers trained by rehab service	☐ Yes / ☐ No
Initial:	Date:

WORK

The following questions will help us assess the financial impact of the stroke, and will be useful in an analysis on how cost-effective the Take Charge session is.

Are you currently in paid employment?	☐ Yes / ☐ No
If yes, what is your current average take-home pay per week?	/ week ☐ Does not wish to disclose

Caregiver Strain Index at twelve months

The following questions should be completed by your next-of-kin / main caregiver. These questions measure the effect of your stroke on their lives. They should tick "YES" for the statements which they agree with, and "NO" for those with which they disagree.

	Yes=1	No=0
Sleep is disturbed (e.g., because_____is in and out of bed or wanders around at night)		
It is inconvenient (e.g., because helping takes so much time or it's a long drive over to help)		
It is a physical strain (e.g., because of lifting in and out of a chair; effort or concentration is required)		
It is confining (e.g., helping restricts free time or cannot go visiting)		
There have been family adjustments (e.g., because helping has disrupted routine; there has been no privacy)		
There have been changes in personal plans (e.g., had to turn down a job; could not go on vacation)		
There have been other demands on my time (e.g., from other family members)		
There have been emotional adjustments (e.g., because of severe arguments)		
Some behaviours are upsetting (e.g., because of incontinence; _____has trouble remembering things; or_____accuses people of taking things)		
It is upsetting to find_____has changed so much from his/her former self (e.g., he/she is a different person than he/she used to be)		
There have been work adjustments (e.g., because of having to take time off)		
It is a financial strain		
Feeling completely overwhelmed (e.g., because of worry about_____; concerns about how you will manage)		
TOTAL SCORE		

BMJ Open The Taking Charge After Stroke (TaCAS) study protocol: a multicentre, investigator-blinded, randomised controlled trial comparing the effect of a single Take Charge session, two Take Charge sessions and control intervention on health-related quality of life 12 months after stroke for non- Māori, non-Pacific adult New Zealanders discharged to community living

Vivian Wai Yin Fu,[1] Mark Weatherall,[2] Harry McNaughton[1]

9   Abstract

Introduction Stroke is one of the leading causes of disability worldwide. Recent data support the possibility that person-centred, self-management interventions can reduce dependence after stroke. However, there is limited information on the generalisability and optimum dose of these interventions.

Methods The Taking Charge After Stroke (TaCAS) study is a multicentre, investigator-blinded, randomised controlled trial recruiting 400 participants following acute stroke from seven hospitals in New Zealand. All patients discharged to community living who have ongoing symptoms at time of discharge (modified Rankin scale>0) will be eligible. Participants will be randomly assigned to one Take Charge session, two Take Charge sessions 6 weeks apart or control.

Outcomes The primary outcome will be the Physical Component Summary score of the Short-Form 36 at 12 months post stroke. Secondary outcomes will include dependence (modified Rankin scale), performance in activities of daily living (Barthel Index) and carer strain (Caregiver Strain Index), at 6 and 12 months post stroke. All analyses will be conducted on an intention-to-treat basis.

Ethics and dissemination The TaCAS study is funded by a Health Research Council of New Zealand grant. It has been approved by the Central Health and Disability Ethics Committee (15/CEN/115). Results will be published and presented at relevant stroke meetings within New Zealand and internationally, informing the use of a self-management intervention after stroke.

Trial registration Australia and New Zealand Clinical Trials Registry ACTRN12615001163594. Date registered 02-11-2015. Medical Research Institute of New Zealand Registry TCS01. Universal trial number U1111-1171-4127.

Strengths and limitations of this study

► This is a trial of a low-cost, practical intervention in the community phase of stroke with the potential to make a significant difference to important outcomes for people with stroke.
► Few exclusion criteria and multicentre design with relatively large number of participants will provide good basis for generalisability of the results.
► Our methodology has stringent safeguards for data quality including a centralised randomisation system, blinded outcomes assessment and an electronic database that tracks all entries and locks data.
► Outcome measurements are obtained by an assessor blinded to allocation; however participants and research clinicians are unable to be blinded, potentially leading to bias.
► The 12–month follow-up limits the study to shorter-term outcomes.

10   Introduction

Stroke is a sudden, devastating clinical event that affects 15 million people worldwide each year, leaving 5 million people permanently

disabled.[1] Some current therapies may modify the acute phase of stroke but their use is inappropriate for a large proportion of patients and their effectiveness is limited.[2 3] Despite early interventions, a high proportion of people have substantial impairment, activity limitation and participation restriction after routine stroke care. At least half of stroke survivors remain dependent on others one year after the stroke.[4] Currently, there is little evidence supporting the effectiveness and efficacy of community-based therapies after stroke. Family support workers and goal-setting strategies are examples of two particular interventions that have been tested in randomised controlled trials but shown no benefit.[5 6] Systematic reviews of therapy-led interventions have shown a positive effect on activities of daily living although with a small effect size.[7]

Self-management intervention studies in stroke and other conditions suggest that there is a positive effect on patient outcomes.[8–10] Self-management programmes differ from education or skills training because they emphasise enablement of individuals to take an active role in managing their condition. This includes management of psychosocial problems and lifestyle changes needed to enhance quality of life.

A successful self-management programme is the 'Take Charge Session' (TCS) intervention, which is a low-cost, person-centred intervention undertaken after discharge from an acute or rehabilitation hospital into the community following acute stroke. This was tested against a DVD-delivered educational intervention and control in the Māori and Pacific Stroke study (MaPSS).[11] In New Zealand, 9000 people suffer stroke every year. Although a relatively small proportion (15%) of those in New Zealand who have a stroke are of Māori or Pacific ethnicity, compared with other ethnic groups in New Zealand, Māori and Pacific stroke patients are more likely to have stroke at a younger age and have poorer outcomes after 12 months, even when adjusted for case-mix.[4]

In more detail MaPSS was a multicentre, randomised controlled trial in which participants were randomised to one of four arms: a TCS (delivered by an ethnic-appropriate, trained layperson), a professionally produced DVD of Māori and Pacific stroke survivor stories, both the TCS and the DVD, or a control group who received written stroke educational material. Outcomes were assessed after 12 months for 80% of the 172 participants. The TCS improved physical health-related quality of life, dependence and caregiver strain. Those who received the TCS session had a Physical Component Score of the Short-Form 36 (PCS) of 6.0 (95% CI 2.0 to 10.0, p=0.004) higher than those who did not. The TCS also reduced dependence on others (modified Rankin scale (mRS) >2) for activities of daily living, OR 0.42 (95% CI 0.2 to 0.89), p=0.023. The number needed to treat to prevent one person becoming dependent was 10.

We hypothesise that the TCS could improve physical outcomes in New Zealand stroke survivors of all ethnicities, and that two exposures to TCS may be more effective than one. This target population for the intervention includes all stroke survivors discharged to community living after inpatient hospital care. This represents about 60% of all patients with acute stroke in New Zealand, which is >5000 people per year. To test this hypothesis, the present study (TaCAS) will determine whether the TCS session improves outcomes in New Zealand stroke survivors who are non-Māori and non-Pacific, and whether two TCS episodes are more effective than one. This paper outlines the study protocol for the TaCAS study and follows the SPIRIT guidelines see online supplementary table.[12]

11 Methods

TaCAS is proposed to be a prospective, single-country, multicentre, parallel-group, blinded outcome assessed, randomised controlled trial of 400 patients with a new diagnosis of acute stroke. Patients will be screened for eligibility by local researchers in seven New Zealand hospitals using the inclusion and exclusion criteria listed in box 1. The screening researcher will be either the stroke nurse or doctors of the stroke team, or the principal investigator depending on the centre. In hospital, this researcher will explain the study and provide a participant information sheet to eligible patients and determine their stroke severity using Barthel Index (BI) at days 3–5 after stroke. In the presence of conditions such as aphasia or cognitive impairment, the patient's ability to understand the study—and therefore to consent—will be determined by the screening researcher. The hospitals are geographically dispersed and range from semirural (secondary) to regional (quaternary) units. The trial study sites are listed in table 1. Māori and Pacific stroke patients have been excluded from TaCAS as it would be unethical to

Table 1 Trial sites

Principal investigator	Centre	City	District Health Board
Dr Harry McNaughton	Wellington Regional Hospital	Wellington	Capital and Coast
Dr Harry McNaughton Dr Tom Thomson	Hutt Hospital	Lower Hutt	Hutt Valley
Dr Carl Hanger	Princess Margaret Hospital/Burwood Hospital	Christchurch	Canterbury
Anna McRae	Auckland City Hospital	Auckland	Auckland
Dr Geoff Green	Middlemore Hospital	South Auckland	Counties Manukau
Dr Anna Ranta	Palmerston North Hospital	Palmerston North	MidCentral
Dr John Gommans	Hawkes Bay Hospital	Hastings	Hawkes Bay

randomise these patients to a control arm when MaPSS demonstrated that they benefit from the intervention.

Patients will receive diagnostic procedures, treatment and rehabilitation as per local practice, not influenced in any way by the study. Patients who express interest in participating will be followed until their date of discharge. Those discharged into community living (not rest home or hospital-level care) will be telephoned within two weeks to arrange a baseline home visit with a research clinician. This research clinician may be a nurse, physiotherapist or occupational therapist, who is trained in the delivery of the TCS. The research clinician must complete this visit within a 16-week window from date of stroke, which allows for time spent in inpatient rehabilitation.

12   Randomisation
At the baseline home visit, the research clinician will explain the study to the participant. Informed consent will be obtained based on the International Conference on Harmonisation Good Clinical Practices guidelines prior to randomisation. No one will consent on behalf of participants in TaCAS, that is, proxy consent is not permitted. Once consented, the research clinician randomises the participant to one of the two interventions or to control by opening a sealed, opaque envelope containing allocation. An independent statistician (MW) is responsible for the computer-generated allocation sequence used to create the envelopes, which are consecutively numbered and delivered to each site in blocks of 18.

Prior to randomisation, all participants undergo a baseline assessment, which includes patient demographics, poststroke dependence measured by the mRS,[13] activities of daily living by the BI,[14] extended activities of daily living by the Frenchay Activities Index (FAI),[15] health-related quality of life by the Short-Form 12 (SF-12v2)[16] and EuroQOL EQ-5D (EQ-5D),[17] depression by the Patient Health Questionnaire-2 (PHQ-2),[18] activation by the Patient Activation Measure (PAM),[19] as well as stroke-related risk factors and medications. Current support, outpatient rehabilitation service involvement and work situation will all be recorded.

After the baseline assessment, but at the same visit, participants receive their allocated intervention: either a TCS or control. The study flow chart is presented in figure 1.

13   Intervention arms
Prior to their involvement in TaCAS, all research clinicians undergo training focused on the rationale and delivery of the TCS. Research clinicians are trained to encourage participants to ask and answer their own questions, and to form their own ideas. Time spent listening to participants is emphasised, in particular allowing them to consider and express their hopes, fears and priorities. By gently reflecting the participant's own thoughts, the TCS attempts to avoid shaping the patient's goals, a process that can occur in therapist-led goal-setting.[20] Research clinicians are discouraged from suggesting goals so that

the focus remains on what the participant wants, rather than what is perceived to be doable. Using a structured workbook allows participants to write down any forthcoming goals and intermediate steps, and to see this as an ongoing process that they can review in their own time; in essence, 'Taking Charge' of their own recovery. The intervention takes between 60 and 80 min to complete. The headings within the workbook include Who I Really Am, Hopes and Aspirations, Main Fears, My Best Day, Physical Needs, Communication, Emotional Issues, Information Needs, Financial Issues, My Support Network and Stroke Prevention. The two intervention arms are distinguished in box 2.

14   Control arm
After the baseline assessment, these participants will receive educational pamphlets produced by the Stroke Foundation of New Zealand. All aspects of routine stroke care, in particular contact with rehabilitation services, will be unchanged by participation.

15   Outcomes
The primary outcome is physical functioning as determined by the PCS of SF-36 at 12 months after stroke.[21] Participants will be followed 6 months after stroke with a questionnaire which will be delivered by telephone, post or by the internet. A blinded outcomes assessor, who will attempt to confirm incomplete responses by a telephone call, will gather all the questionnaire information. At 12 months after stroke, the blinded outcomes assessor will visit participants in person to complete follow-up. Box 3 describes the primary and secondary outcomes as well as the predefined subgroup analyses.

The SF-36 is a psychometrically robust self-reported measure of health status that is validated in multiple conditions, including stroke. The PCS assigns weights to responses about physical ability, the impact of physical health, pain and general health perceptions to give a composite score. The PCS score has an observed mean of between 38 and 39, 12 months after stroke in Australasian stroke studies.[22] It was responsive to the TCS in the MaPSS study, in which the difference between mean-adjusted 12-month PCS scores exceeded the Minimal Clinically Important Difference of 5 points.

Table 2 summarises timing of the assessments. Research clinicians will write data from their visits onto paper forms, which are then scanned and sent to the data management team for entry onto a secure, online database. Each participant is identified by a unique identifier with only the central site at the Medical Research Institute of New Zealand (MRINZ) holding the master log of names.

Attempts will be made to obtain mRS and SF-36 data at 12 months by telephone from participants who discontinue or deviate from the intervention protocol. If this is not possible, data about living situation and level of disability (mRS) will be obtained from the participant's general practitioner.
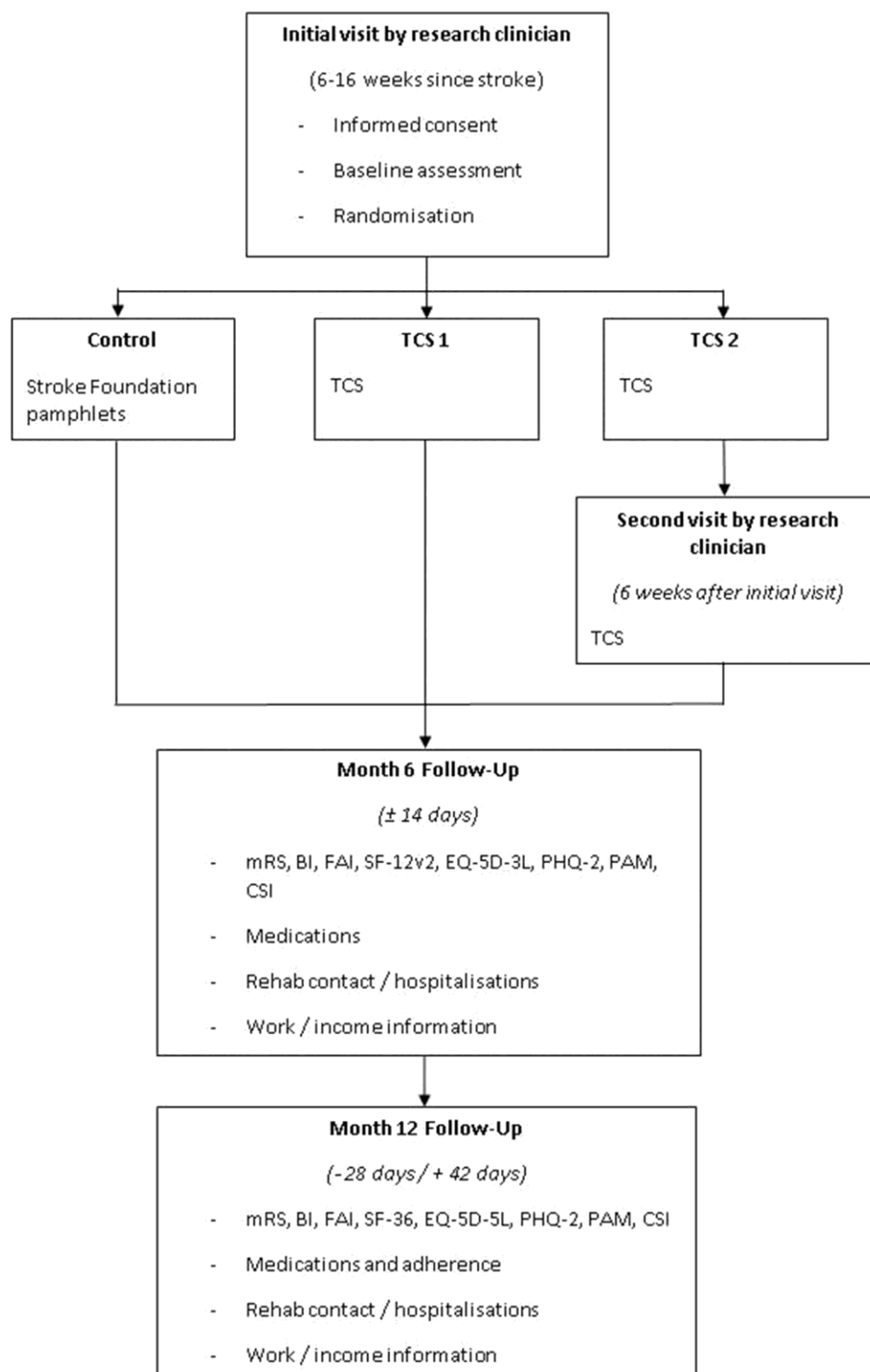
Figure 1 TaCAS study flow chart depicting interventions and outcome measurements. BI, Barthel Index; CSI, Caregiver Strain Index; EQ-5D-5L, EuroQol 5-Dimensional, 5 Levels; FAI, Frenchay Activities Index; mRS, modified Rankin scale; PAM, Patient Activation Measure; PHQ-2, Patient Health Questionnaire 2; SF-12v2, Short Form 12 version 2; SF-36, Short Form 36; TCS, Take Charge Session.

16   Risks to Internal Validity

The main risks to internal validity are threats to the fidelity of the intervention and unblinding. Site initiation and subsequent site training visits by the Coordinating Investigator, as well as 6-monthly teleconferences between research clinicians and the study team, will allow monitoring of the fidelity of the TCS. Research clinicians are encouraged to document specific problems encountered

Box 1 Inclusion and exclusion criteria

Inclusion criteria

► Non-Māori, non-Pacific adults >16 years of age with acute ischaemic stroke or intracerebral haemorrhage (WHO definition)
► Discharged from hospital to non-institutional, community living situation
► Modified Rankin score >0

Exclusion criteria

► Inability to provide informed consent

during the TCS although the participant keeps the TCS workbook as part of the intervention. Due to the personal nature of its contents, the workbook will not be collected or analysed. A central email account is checked daily for questions from research clinicians, and the principal investigator will answer urgent questions immediately by telephone. These queries form a Frequently Asked Questions section in a monthly newsletter to all the sites.

Blinding is maintained by employing a single-blinded outcomes assessor who will visit participants at each site. The blinded outcomes assessor will have an office that is physically separate from the office of the local research clinicians, and the specific online database user profile allows access only to demographic and outcomes data. Participants are asked not to disclose details of home visits to the blinded outcomes assessor, and intervention participants are asked to hide the TCS workbook when the blinded outcomes assessor visits.

17   Sample size calculation and statistical analysis

In MaPSS, the root mean square error for the PCS was 10.8. The clinically significant difference for PCS is five. A total sample size of 360, 120 in each of three arms, has 90% power to detect this difference. With provision for 10% drop out, we plan to recruit 400 participants. Experience in MaPSS has allowed prediction that TaCAS will complete recruitment in mid-2017.

All outcomes will be analysed using the intention-to-treat principle. Our primary analysis of the difference in mean PCS (between both Take Charge groups and control, and between high-dose Take Charge and low-dose Take charge) will be by analysis of variance. We will use analysis

Box 2 Interventions

1 TCS
► A person-centred, self-directed session designed to engage the participant in the process of recovery, guided by a workbook. The research clinician is trained to facilitate the process by listening and supporting any forthcoming ideas.
2 TCS second arm
► The initial TCS will be undertaken, followed by a second TCS approximately six weeks after. The second 'dose' of the session allows time for the participant to express new, interim ideas that may have formed, and to reflect upon their progress.

Box 3 Primary and secondary outcomes and proposed subgroup analyses for the Taking Charge After Stroke study

Primary outcome

► Physical Component Summary score of Short-Form 36 at 12 months after stroke

Secondary outcomes

At 6 months after stroke

Telephone-based, written postal or internet-administered questionnaire assessment of
► Physical Component Summary score of the Short-Form 12 version 2 (PCS of SF-12v2)
► Activities of daily living: Barthel Index (BI)
► Instrumental activities of daily living: Frenchay Activities Index (FAI)
► Level of function: modified Rankin scale (mRS)
► Depression: Patient Health Questionnaire-2 (PHQ-2)
► Level of activation: Patient Activation Measure (PAM)
► Health-Related Quality of Life: WHO Quality of Life Assessment and euroQol Five-Dimensional scores (EuroQOL EQ-5D)
► Carer strain: Caregiver Strain Index (CSI)
► Contact with rehabilitation service
► Hospitalisations

At 12 months after stroke

Face-to-face assessment of

► BI, FAI, mRS, PHQ-2, PAM, EuroQOL EQ-5D, CSI, rehabilitation contact or hospitalisations
Predefined subgroups

► Stroke severity: patients with BI at 3–5 days after stroke grouped severe (0–7), moderate (8–13) and mild (14–20)
► Sites (all centres and tertiary centre vs not)

of covariance (ANCOVA) to analyse the Take Charge dose response as a continuous predictor. A further analysis will adjust for baseline variables including baseline PCS, age and gender. We will use also ANCOVA for our prespecified subgroup analyses using an interaction term between randomised treatment and each of stroke severity, site, age, gender, living situation, type of stroke, thrombolysis and fluoxetine use. The mRS will be analysed as dichotomous (0–2 compared with 3–5) and by ordinal logistic regression.

We plan to undertake a meta-analysis of individual patient data from TaCAS and the MaPSS study to compare the TCS against control, using PCS at 12 months after stroke in a linear mixed model meta-analysis. We will also assess combined dependency based on mRS in a generalised linear mixed model.

Finally, we will undertake a cost-utility analysis of the TCS using employment and earning information, cost to the carer and health-related quality of life.

Table 2 Timing of assessments

	Randomisation (visit 1)	1/3 have 2 TCS (visit 2)	Follow-up 1	Follow-up 2
Time since stroke	6–12 weeks	6 weeks after randomisation	6 months	12 months
Clinical examination and risk factors*	X	X		X
Current medications	X		X	X
Medication adherence				X
Rehabilitation, support, work information	X	X	X	X
SF-36v2				X
SF-12v2	X	X	X	
mRS, BI, FAI, PHQ-2, EuroQOL EQ-5D, PAM, CSI	X	X	X	X

*Includes heart rate, heart rhythm, blood pressure, height and weight, smoking status, diabetes, anticoagulation status.
BI, Barthel Index; CSI, Caregiver Strain Index; EQ-5D, euroQol Five-Dimensional scores; FAI, Frenchay Activities Index; mRS, modified Rankin scale; PAM, Patient Activation Measure; PHQ-2, Patient Health Questionnaire-2; SF-12v2, Short-Form 12 version 2; SF-36v2, Short-Form 36 version 2; TCS, Take Charge Session.

18   Data collection and study management

The baseline data will be collected on paper forms by research clinicians at the initial home visits. These forms are scanned and sent to the data management team based at MRINZ for entry into a secure, online database. This database is designed to maintain complete blinding of the outcomes assessor. The data management team at MRINZ performs double data entry of the baseline visit data. Participants undertaking the 6-month questionnaire online will enter their data directly onto this database. The blinded outcomes assessor will enter the 6-month data obtained by telephone or posted questionnaire. The blinded outcomes assessor will also enter the 12-month data onto the database by an electronic tablet at the final home visit. This web-based data management system allows allocation concealment, locking of completed entries and ad hoc consistency checks by study monitors.

The TCS has no known harms associated. We plan to report the following serious adverse events (SAEs): death, life-threatening event, permanently disabling or incapacitating event, hospitalisation and any significant medical event considered serious by the study investigator. All SAEs will be reported to the New Zealand Central Health and Disability Ethics Committee of New Zealand (HDEC) in accordance with current guidelines, as well as to the MRINZ within 24 hours of the study investigators becoming aware of the event. AE data are collected at each follow-up and during the study period if the participant or their next-of-kin notify the research team. No interim analysis, for either effectiveness or harm, is planned prior to completion of the study. There are no current data available for data sharing.

There are no specific plans for independent auditing of this study; however, MRINZ research staff and online database will ensure there is a complete audit trail for external auditing, in the event this is required.

19   Ethics and dissemination

TaCAS will be conducted in compliance with relevant New Zealand legislation including the Health Information Privacy Code, the Health and Disability Code and the New Zealand Bill of Rights Act. Ethics approval has been provided by the HDEC, reference 15/CEN/115 and at the research office at each local site. Protocol amendments will first be approved by the HDEC and then by local ethics committees before implementation. The current approved protocol version is version 9.1, dated 20 February 2017.

Research clinicians will obtain informed consent from the participant when understanding of the study's undertakings has been demonstrated. The participant 'making a mark' on the consent form will be accepted. Proxy consent by a surrogate will not be accepted.

To maintain confidentiality, participant information will be kept in the locked, central data office at MRINZ as well as at each local site in locked offices. The online database is password-protected and located on an encrypted server belonging to REDCap. Source data from TaCAS will be kept in secure premises for 15 years after completion of the study, then it will be destroyed.

The day-to-day management of the trial is undertaken by a management committee comprised of the principal investigator, Dr Harry McNaughton, the study coordinator, Dr Vivian Fu, project manager, Tanya Baker, and a team of researchers based at MRINZ. These individuals, as well as our statistician, Dr Mark Weatherall, will have access to the final trial dataset. The TaCAS Study Group meets on an 'as-required' basis with regular updates via newsletters and email. The majority of members meet regularly for national stroke and rehabilitation working groups, study days and conferences where progress and issues with the trial are discussed. Neither the principal investigator nor site investigators have competing interests.

All members of the TaCAS Study Group will contribute to, and be acknowledged in, the primary trial manuscript. The HRC funding will be acknowledged in all publications. Results will also be presented at national and international stroke meetings, including the National Stroke Rehabilitation Working Group and National Stroke Clinical Working Group meetings. Those participants who have indicated their desire to receive results of the study will have these sent to them.

20 Trial status

The first patient was randomised on 24 October 2015 and recruitment is expected to complete by June 2017. Study recruitment is continuing as planned.

Author affiliations
[1]Medical Research Institute of New Zealand, Wellington, New Zealand
[2]University of Otago, Wellington, New Zealand

21 References

1. Outpatient Service Trialists. Stroke | world heart federation [Internet].http://www.world-heart-federation.org/cardiovascular-health/stroke/ (cited 2016 Aug 15).
2. Wardlaw JM, Murray V, Berge E, *et al.* Thrombolysis for acute ischaemic stroke. *Cochrane database Syst Rev [Internet].* 2014;7:CD000213. http://www.cochrane.org/CD000213/STROKE_ clot-dissolving-drugs-treating-ischaemic-stroke-early-stages.
3. Rodrigues FB, Neves JB, Caldeira D, *et al.* Endovascular treatment versus medical care alone for ischaemic stroke: systematic review and meta-analysis. *BMJ [Internet]* 17542016 Apr 18 http://www.bmj.com/content/353/bmj.i1754.abstract (cited 2017 Jan 29).
4. McNaughton H, Weatherall M, McPherson K, *et al.* The comparability of community outcomes for european and non-European survivors of stroke in New Zealand. *N Z Med J* 2002;115:98–100.
5. Ellis G, Mant J, Langhorne P, *et al.* Stroke liaison workers for stroke patients and carers: an individual patient data meta-analysis. *Cochrane Database Syst Rev* 2010;5:CD005066 http://www.ncbi. nlm.nih.gov/pubmed/20464736.
6. Levack WM, Weatherall M, Hay-Smith EJ, *et al.* Goal setting and strategies to enhance goal pursuit for adults with acquired disability participating in rehabilitation. *Cochrane Database Syst Rev* 2015;7:CD009727. http://www.ncbi.nlm.nih.gov/pubmed/26189709.
7. Therapy-based rehabilitation services for stroke patients at home. *Cochrane Database Syst Rev* 2003;1:CD002925. http://www.ncbi. nlm.nih.gov/pubmed/12535444.
8. Parke HL, Epiphaniou E, Pearce G, *et al.* Self-Management support interventions for stroke survivors: a systematic Meta-Review. *PLoS One* 2015;10:e0131448–23.
9. Lorig KR, Ritter P, Stewart AL, *et al.* Chronic disease self-management program: 2-year health status and health care utilization outcomes. *Med Care* 2001;39:1217–23. http://www.ncbi. nlm.nih.gov/pubmed/11606875.
10. A rapid synthesis of the evidence on interventions supporting self-management for people with long-term conditions:. *PRISMS Practical systematic Review of Self-Management Support for long-term conditions* 2014.
11. Harwood M, Weatherall M, Talemaitoga A, *et al.* Taking charge after stroke: promoting self-directed rehabilitation to improve quality of life--a randomized controlled trial. *Clin Rehabil* 2012;26:493–501.
12. Chan AW, Tetzlaff JM, Gøtzsche PC, *et al.* SPIRIT 2013 explanation and elaboration: guidance for protocols of clinical trials. *Bmj* 2013;346:e7586. http://www.pubmedcentral.nih.gov/articlerender. fcgi?artid=3541470&tool=pmcentrez&rendertype=abstract.
13. van Swieten JC, Koudstaal PJ, Visser MC, *et al.* Interobserver agreement for the assessment of handicap in stroke patients. *Stroke* 1988;19:604–7. http://www.ncbi.nlm.nih.gov/pubmed/3363593.
14. Mahoney FI, Barthel DW. Functional evaluation: the Barthel index. *Md State Med J* 1965;14:61–5. http://www.ncbi.nlm.nih.gov/ pubmed/14258950.
15. Wade DT, Legh-Smith J, Langton Hewer R. Social activities after stroke: measurement and natural history using the frenchay activities index. *Int Rehabil Med* 1985;7:176–81. http://www.ncbi.nlm.nih.gov/ pubmed/4093249.
16. Bohannon RW, Maljanian R, Lee N, *et al.* Measurement properties of the short form (SF)-12 applied to patients with stroke. *Int J Rehabil Res* 2004;27:151–4. http://www.ncbi.nlm.nih.gov/pubmed/15167114.
17. Dorman PJ, Waddell F, Slattery J, *et al.* Is the EuroQol a valid measure of health-related quality of life after stroke? *Stroke* 1997;28:1876–82. http://www.ncbi.nlm.nih.gov/pubmed/9341688.
18. Kroenke K, Spitzer RL, Williams JB. The patient health Questionnaire-2: validity of a two-item depression screener. *Med Care* 2003;41:1284–92. http://www.ncbi.nlm.nih.gov/pubmed/14583691.
19. Hibbard JH, Stockard J, Mahoney ER, *et al.* Development of the patient activation measure (PAM): conceptualizing and measuring activation in patients and consumers. *Health Serv Res* 2004;39(4 Pt 1):1005–26. http://www.pubmedcentral.nih.gov/articlerender.fcgi? artid=1361049&tool=pmcentrez&rendertype=abstract.
20. Levack WM, Taylor K, Siegert RJ, *et al.* Is goal planning in rehabilitation effective? A systematic review. *Clin Rehabil* 2006;20:739–55.
21. Anderson C, Laubscher S, Burns R. Validation of the short form 36 (SF-36) health survey questionnaire among stroke patients. *Stroke* 1996;27:1812–6. http://www.ncbi.nlm.nih.gov/pubmed/8841336.
22. McNaughton HK, Weatherall M, McPherson KM. Functional measures across neurologic disease states: analysis of factors in common. *Arch Phys Med Rehabil* 2005;86:2184–8. http://www.archives-pmr.org/article/S0003999305005630/fulltext.

This Agreement between Dr. Vivian Fu ("You") and BMJ Publishing Group Ltd. ("BMJ Publishing Group Ltd.") consists of your license details and the terms and conditions provided by BMJ Publishing Group Ltd. and Copyright Clearance Center.

License Number	4472761249163
License date	Nov 19, 2018
Licensed Content Publisher	BMJ Publishing Group Ltd.
Licensed Content Publication	BMJ Open
Licensed Content Title	The Taking Charge After Stroke (TaCAS) study protocol: a multicentre, investigator-blinded, randomised controlled trial comparing the effect of a single Take Charge session, two Take Charge sessions and control intervention on health-related quality of life 12 months after stroke for non-Māori, non-Pacific adult New Zealanders discharged to community living
Licensed Content Author	Vivian Wai Yin Fu, Mark Weatherall, Harry McNaughton
Licensed Content Date	May 1, 2017
Licensed Content Volume	7
Licensed Content Issue	5
Type of Use	Dissertation/Thesis
Requestor type	Author of this article
Format	Print
Portion	Full text
Will you be translating?	No
Circulation/distribution	5
Title of your thesis / dissertation	Take Charge After Stroke: A Novel Intervention To Improve Community Stroke Outcomes
Expected completion date	Nov 2018
Estimated size(pages)	300
Requestor Location	Dr. Vivian Fu 301/181 Tasman Street Wellington, Wellington 6021 New Zealand Attn: Dr. Vivian Fu
Publisher Tax ID	GB674738491
Billing Type	Invoice

Terms and Conditions

BMJ Group Terms and Conditions for Permissions

When you submit your order you are subject to the terms and conditions set out below. You will also have agreed to the Copyright Clearance Center's ("CCC") terms and conditions regarding billing and payment https://s100.copyright.com/App/PaymentTermsAndConditions.jsp. CCC are acting as the BMJ Publishing Group Limited's ("BMJ Group's") agent.

Subject to the terms set out herein, the BMJ Group hereby grants to you (the Licensee) a non-exclusive, non-transferable licence to re-use material as detailed in your request for this/those purpose(s) only and in accordance with the following conditions:

1) **Scope of Licence:** Use of the Licensed Material(s) is restricted to the ways specified by you during the order process and any additional use(s) outside of those specified in that request, require a further grant of permission.

2) **Acknowledgement:** In all cases, due acknowledgement to the original publication with permission from the BMJ Group should be stated adjacent to the reproduced Licensed Material. The format of such acknowledgement should read as follows:

"Reproduced from [publication title, author(s), volume number, page numbers, copyright notice year] with permission from BMJ Publishing Group Ltd."

3) **Third Party Material**: BMJ Group acknowledges to the best of its knowledge, it has the rights to licence your reuse of the Licensed Material, subject always to the caveat that images/diagrams, tables and other illustrative material included within, which have a separate copyright notice, are presumed as excluded from the licence. Therefore, you should ensure that the Licensed Material you are requesting is original to BMJ Group and does not carry the copyright of another entity (as credited in the published version). If the credit line on any part of the material you have requested in any way indicates that it was reprinted or adapted by BMJ Group with permission from another source, then you should seek permission from that source directly to re-use the Licensed Material, as this is outside of the licence granted herein.

4) **Altering/Modifying Material:** The text of any material for which a licence is granted may not be altered in any way without the prior express permission of the BMJ Group. Subject to Clause 3 above however, single figure adaptations do not require BMJ Group's approval; however, the adaptation should be credited as follows:

"Adapted by permission from BMJ Publishing Group Limited. [publication title, author, volume number, page numbers, copyright notice year]

5) **Reservation of Rights:** The BMJ Group reserves all rights not specifically granted in the combination of (i) the licence details provided by you and accepted in the course of this licensing transaction, (ii) these terms and conditions and (iii) CCC's Billing and Payment Terms and Conditions.

6) **Timing of Use:** First use of the Licensed Material must take place within 12 months of the grant of permission.

7). **Creation of Contract and Termination:** Once you have submitted an order via Rights link and this is received by CCC, and subject to you completing accurate details of your proposed use,

this is when a binding contract is in effect and our acceptance occurs. As you are ordering rights from a periodical, to the fullest extent permitted by law, you will have no right to cancel the contract from this point other than for BMJ Group's material breach or fraudulent misrepresentation or as otherwise permitted under a statutory right. Payment must be made in accordance with CCC's Billing and Payment Terms and conditions. In the event that you breach any material condition of these terms and condition or any of CCC's Billing and Payment Terms and Conditions, the license is automatically terminated upon written notice from the BMJ Group or CCC or as otherwise provided for in CCC's Billing and Payment Terms and Conditions, where these apply.. Continued use of materials where a licence has been terminated, as well as any use of the Licensed Materials beyond the scope of an unrevoked licence, may constitute intellectual property rights infringement and BMJ Group reserves the right to take any and all action to protect its intellectual property rights in the Licensed Materials.

8. **Warranties:** BMJ Group makes no express or implied representations or warranties with respect to the Licensed Material and to the fullest extent permitted by law this is provided on an "as is" basis. For the avoidance of doubt BMJ Group does not warrant that the Licensed Material is accurate or fit for any particular purpose.

9. **Limitation of Liability:** To the fullest extent permitted by law, the BMJ Group disclaims all liability for any indirect, consequential or incidental damages (including without limitation, damages for loss of profits, information or interruption)arising out of the use or inability to use the Licensed Material or the inability to obtain additional rights to use the Licensed Material. To the fullest extent permitted by law, the maximum aggregate liability of the BMJ Group for any claims, costs, proceedings and demands for direct losses caused by BMJ Group's breaches of its obligations herein shall be limited to twice the amount paid by you to CCC for the licence granted herein.

10. **Indemnity:** You hereby indemnify and hold harmless the BMJ Group and their respective officers, directors, employees and agents, from and against any and all claims, costs, proceeding or demands arising out of your unauthorised use of the Licensed Material.

11. **No Transfer of License:** This licence is personal to you, and may not be assigned or transferred by you without prior written consent from the BMJ Group or its authorised agent(s). BMJ Group may assign or transfer any of its rights and obligations under this Agreement, upon written notice to you.

12. **No Amendment Except in Writing:** This licence may not be amended except in a writing signed by both parties (or, in the case of BMJ Group, by CCC on the BMJ Group's behalf).

13. **Objection to Contrary terms:** BMJ Group hereby objects to any terms contained in any purchase order, acknowledgment, check endorsement or other writing prepared by you, which terms are inconsistent with these terms and conditions or CCC's Billing and Payment Terms and Conditions. These terms and conditions, together with CCC's Billing and Payment Terms and Conditions (which to the extent they are consistent are incorporated herein), comprise the entire agreement between you and BMJ Group (and CCC) and the Licensee concerning this licensing transaction. In the event of any conflict between your obligations established by these terms and conditions and those established by CCC's Billing and Payment Terms and Conditions, these terms and conditions shall control.

14. **Revocation:** BMJGroup or CCC may, within 30 days of issuance of this licence, deny the permissions described in this licence at their sole discretion, for any reason or no reason, with a full refund payable to you should you have not been able to exercise your rights in full. Notice of such denial will be made using the contact information provided by you. Failure to receive such notice from BMJGroup or CCC will not, to the fullest extent permitted by law alter or invalidate

the denial. For the fullest extent permitted by law in no event will BMJ Group or CCC be responsible or liable for any costs, expenses or damage incurred by you as a result of a denial of your permission request, other than a refund of the amount(s) paid by you to BMJ Group and/or CCC for denied permissions.

15. **Restrictions to the license**:

15.1 Promotion: BMJ Group will not give permission to reproduce in full or in part any Licensed Material for use in the promotion of the following:

a) non-medical products that are harmful or potentially harmful to health: alcohol, baby milks and/or, sunbeds

b) medical products that do not have a product license granted by the Medicines and Healthcare products Regulatory Agency (MHRA) or its international equivalents. Marketing of the product may start only after data sheets have been released to members of the medical profession and must conform to the marketing authorization contained in the product license.

16.   Translation: This permission is granted for non-exclusive world English language rights only unless explicitly stated in your licence. If translation rights are granted, a professional translator should be employed and the content should be reproduced word for word preserving the integrity of the content.

17.   **General:** Neither party shall be liable for failure, default or delay in performing its obligations under this Licence, caused by a Force Majeure event which shall include any act of God, war, or threatened war, act or threatened act of terrorism, riot, strike, lockout, individual action, fire, flood, drought, tempest or other event beyond the reasonable control of either party.

17.1   In the event that any provision of this Agreement is held to be invalid, the remainder of the provisions shall continue in full force and effect.

17.2   There shall be no right whatsoever for any third party to enforce the terms and conditions of this Agreement. The Parties hereby expressly wish to exclude the operation of the Contracts (Rights of Third Parties) Act 1999 and any other legislation which has this effect and is binding on this agreement.

17.3   To the fullest extent permitted by law, this Licence will be governed by the laws of England and shall be governed and construed in accordance with the laws of England. Any action arising out of or relating to this agreement shall be brought in courts situated in England save where it is necessary for BMJ Group for enforcement to bring proceedings to bring an action in an alternative jurisdiction.